

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4
5 -----) Master File
6 IN RE: ETHICON, INC. PELVIC) No. 2:12-MD-02327
7 REPAIR SYSTEM PRODUCTS LIABILITY) MDL 2327
8 LITIGATION)
9 -----)
10 THIS DOCUMENT RELATES TO ALL) JOSEPH R. GOODWIN
11 WAVE 8 AND SUBSEQUENT WAVE CASES) US DISTRICT JUDGE
12 AND PLAINTIFFS)
13 -----)

14
15 The deposition of PETER K. SAND, M.D.,
16 called for examination, taken pursuant to the Federal
17 Rules of Civil Procedure of the United States District
18 Courts pertaining to the taking of depositions, taken
19 before JULIANA F. ZAJICEK, a Registered Professional
20 Reporter and a Certified Shorthand Reporter, at
21 NorthShore Medical Group, Suite 300, 15 Tower Court,
22 Gurnee, Illinois, on September 26, 2018, at 9:00 a.m.
23
24

Peter K. Sand, M.D.

<p style="text-align: right;">Page 2</p> <p>1 PRESENT:</p> <p>2</p> <p>3 ON BEHALF OF THE PLAINTIFFS:</p> <p>4 WAGSTAFF & CARTMELL, LLP</p> <p>5 4740 Grand Avenue, Suite 300</p> <p>6 Kansas City, Missouri 64112</p> <p>7 816-531-2372</p> <p>8 BY: DIANE K. WATKINS, ESQ.</p> <p>9 dwatkins@wcllp.com</p> <p>10</p> <p>11 ON BEHALF OF THE DEFENDANTS:</p> <p>12 BUTLER SNOW LLP</p> <p>13 500 Office Center Drive, Suite 400</p> <p>14 Fort Washington, Pennsylvania 19034</p> <p>15 267-513-1885</p> <p>16 BY: NILS B. (BURT) SNELL, ESQ.</p> <p>17 burt.snell@butlersnow.com</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22 REPORTED BY: JULIANA F. ZAJICEK, C.S.R. NO. 84-2604.</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 4</p> <p>1 EXHIBITS (Continued)</p> <p>2 SAND EXHIBIT MARKED FOR ID</p> <p>3 No. 5 E-mail chain; ETH.MESH.05134613 - 6</p> <p>4 614</p> <p>5 No. 6 E-mail, Subject: Dr. Peter Sands' 6</p> <p>6 Advances in Urogynecology</p> <p>7 Conference - June 8-10;</p> <p>8 ETH.MESH.01717762 - 764</p> <p>9 No. 7 Article entitled: "An 6</p> <p>10 International Urogynecological</p> <p>11 Association (IUGA)/International</p> <p>12 Continence Society (ICS) joint</p> <p>13 terminology and classification of</p> <p>14 the complications related directly</p> <p>15 to the insertion of prostheses</p> <p>16 (meshes, implants, tapes) & grafts</p> <p>17 in female pelvic floor surgery"</p> <p>18 No. 8 E-mail, Subject: Gynecare Status 6</p> <p>19 Report - September;</p> <p>20 ETH.MESH.07728851 - 859</p> <p>21 No. 9A Letter from Dr. Sand to Burt Snell 12</p> <p>22 6/17/18</p> <p>23 No. 9B Letter from Dr. Sand to Burt Snell 12</p> <p>24 7/30/18</p>
<p style="text-align: right;">Page 3</p> <p>1 INDEX</p> <p>2</p> <p>3 WITNESS: PAGE:</p> <p>4 PETER K. SAND, M.D.</p> <p>5 EXAM BY MS. WATSON..... 6</p> <p>6 EXAM BY MR. SNELL..... 112</p> <p>7 FURTHER EXAM BY MS. WATSON..... 122</p> <p>8 FURTHER EXAM BY MR. SNELL..... 126</p> <p>9</p> <p>10 *****</p> <p>11</p> <p>12 EXHIBITS</p> <p>13 SAND EXHIBIT MARKED FOR ID</p> <p>14 No. 1 Notice to take Deposition of 6</p> <p>15 Dr. Peter Sand</p> <p>16 No. 2 General Expert Report of Peter K. 6</p> <p>17 Sand, M.D.</p> <p>18 No. 3A Curriculum Vitae 6</p> <p>19 No. 3B Update Curriculum Vitae 6</p> <p>20 No. 4A General Reliance List in Addition 6</p> <p>21 to Materials Referenced in Report</p> <p>22 No. 4B Supplemental General Materials 6</p> <p>23 List in Addition to Materials</p> <p>24 Referenced in Report</p>	<p style="text-align: right;">Page 5</p> <p>1 EXHIBITS (Continued)</p> <p>2 SAND EXHIBIT MARKED FOR ID</p> <p>3 No. 10 Thumb drive containing materials 12</p> <p>4 considered by Dr. Sand</p> <p>5 No. 11 Dr. Sand's file 20</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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<p style="text-align: right;">Page 6</p> <p>1 (WHEREUPON, a certain document was 2 marked Sand Deposition Exhibit No. 1, 3 No. 2, No. 3A, No. 3B, No. 4A, 4 No. 4B, No. 5, No. 6, No. 7 and 5 No. 8, for identification, as of 6 09/26/2018.) 7 (WHEREUPON, the witness was duly 8 sworn.) 9 PETER K. SAND, M.D., 10 called as a witness herein, having been first duly 11 sworn, was examined and testified as follows: 12 EXAMINATION 13 BY MS. WATSON: 14 Q. All right. Doctor, will you please state 15 your name for the record? 16 A. Peter Sand. 17 Q. And you are a medical doctor, correct? 18 A. I am, yes. 19 Q. What is your specialty? 20 A. I am trained as an 21 obstetrician/gynecologist and board certified in that 22 and also trained as a urogynecologist and 23 board certified in female pelvic medicine and 24 reconstructive surgery.</p>	<p style="text-align: right;">Page 8</p> <p>1 today? 2 MR. SNELL: Object; form. 3 Go ahead. 4 BY THE WITNESS: 5 A. I am here, I believe, as an expert for the 6 defense in this case. 7 BY MS. WATSON: 8 Q. And who is the defense? 9 A. The defense would be Ethicon Gynecare. 10 Q. Okay. Do you have an understanding as to 11 which law firm retained you? 12 A. I do, yes. 13 Q. And who is that? 14 A. That -- well, it was specifically Burt 15 Snell at Butler Snow. 16 Q. And have you ever worked with Butler Snow 17 before? 18 A. I have not before this occasion. 19 Q. Have you worked for any other law firms 20 representing mesh manufacturers in the transvaginal 21 mesh litigation? 22 MR. SNELL: Object; form. 23 Counsel, I think you said "worked for." 24 BY MS. WATSON:</p>
<p style="text-align: right;">Page 7</p> <p>1 Q. How long have you been practicing 2 medicine? 3 A. Well, I graduated from medical school in 4 1980. 5 Q. Okay. 6 A. So since that time. 7 Q. And how long have you been board certified 8 as a urogynecologist? 9 A. Since -- well, since -- yes, since 10 certification was available in 2013. I took my boards 11 that first year and passed. 12 Q. My name is Diane Watkins. I represent the 13 Plaintiffs in this matter. 14 Do you understand that? 15 A. I do, as you've told me, yes. 16 Q. Okay. And obviously I'm appearing by 17 phone. If at any time you cannot hear me or 18 understand me, will you please let me know? 19 A. I will. Yeah, your voice is a little 20 garbled sometimes, so I will ask you to repeat 21 questions if I can't understand them. 22 Q. I appreciate that. And I will try to 23 enunciate due to the circumstances. 24 Do you understand what your role is here</p>	<p style="text-align: right;">Page 9</p> <p>1 Q. Been retained by? 2 MR. SNELL: Okay. So can we just -- 3 MS. WATSON: I can rephrase my question. 4 MR. SNELL: Thank you. 5 BY MS. WATSON: 6 Q. Sir, have you been retained by any other 7 law firms representing transvaginal mesh manufacturers 8 in the mesh litigation? 9 MR. SNELL: And I'm just going to put a 10 cautionary note because I'm not aware of all of this. 11 I'm going to caution the doctor, to the extent there 12 is a privileged relationship where you have not been 13 disclosed as an expert, you should not identify that. 14 THE WITNESS: Thank you. 15 BY THE WITNESS: 16 A. I've been retained by Reed Smith in the 17 defense of what used to be American Medical Systems. 18 BY MS. WATSON: 19 Q. Okay. Did you draft any expert reports in 20 that capacity? 21 A. Yes, I have. 22 Q. Were those, to your knowledge, general 23 expert reports or case-specific expert reports or 24 both?</p>

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<p>1 A. Both.</p> <p>2 Q. With respect to the general expert</p> <p>3 reports, how many did you do, to your knowledge?</p> <p>4 A. I'm not sure I know how to answer that</p> <p>5 accurately. I have worked now with Reed Smith on two</p> <p>6 waves of cases and so I've submitted a general report</p> <p>7 in both of those instances, but there were multiple</p> <p>8 individual complaints/cases involved.</p> <p>9 Q. With respect to your general reports, what</p> <p>10 products did you cover?</p> <p>11 A. These were all midurethral sling cases.</p> <p>12 Q. And did you give a deposition in any of</p> <p>13 the AMS cases for the general AMS litigation?</p> <p>14 A. I have not.</p> <p>15 Q. All right. Bear with me, Doctor, there</p> <p>16 may be times when it is silent. It is just because</p> <p>17 I'm going through my outline.</p> <p>18 The court reporter will put in front of</p> <p>19 you what we've marked as Exhibit No. 1. It is the</p> <p>20 notice to take your deposition here today.</p> <p>21 Have you seen this document before?</p> <p>22 A. Yes, I received it several days ago.</p> <p>23 MR. SNELL: Counsel -- Counsel, I just need to</p> <p>24 make a statement. I can't tell if this is -- this</p>	<p>1 Q. Okay. And have you brought the responsive</p> <p>2 materials to the extent that they exist?</p> <p>3 A. Yes, I have. As I think you heard us, I</p> <p>4 gave an updated curriculum vitae to the court reporter</p> <p>5 which she has marked as Exhibit 3B and I have a thumb</p> <p>6 drive of all of the materials I've considered in</p> <p>7 making my report. Oh, and also the two invoices that</p> <p>8 I've sent to Mr. Snell at Butler Snow for my work.</p> <p>9 Q. Okay. Thank you for that.</p> <p>10 So as I understand it, you have an updated</p> <p>11 CV which we've marked as 3B and then your thumb drive</p> <p>12 contains the documents that are listed on your two</p> <p>13 reliance lists, is that correct?</p> <p>14 A. Yes, it is.</p> <p>15 Q. And then with respect to the two invoices,</p> <p>16 can you tell me --</p> <p>17 MS. WATSON: And, Madam Court Reporter, can we</p> <p>18 go ahead and mark those as, I think we are up to</p> <p>19 No. 9, if you don't mind, 9A and B for the invoices.</p> <p>20 And if we can mark the, I guess the thumb drive as 10.</p> <p>21 (WHEREUPON, a certain document was</p> <p>22 marked Sand Deposition Exhibit</p> <p>23 No. 9A, No. 9B and No. 10, for</p> <p>24 identification, as of 09/26/2018.)</p>
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<p>1 looks like the older deposition. I believe there was</p> <p>2 an amended deposition notice that was to be filed</p> <p>3 because this notice improperly states that this, if I</p> <p>4 saw it somewhere, was a 30(b)(6) deposition, and just</p> <p>5 so the record is clear, this witness is presenting on</p> <p>6 his Rule 26 expert report to be deposed. He has not</p> <p>7 been identified by Ethicon or Johnson & Johnson, the</p> <p>8 Defendants, as a 30(b)(6) witness, so...</p> <p>9 MS. WATSON: Understood. And we did file a</p> <p>10 deposition notice on September 24th, but your</p> <p>11 statement is acknowledged. I understand that he is</p> <p>12 here as a general expert witness and not a 30(b)(6)</p> <p>13 witness.</p> <p>14 BY MS. WATSON:</p> <p>15 Q. Doctor, if you don't mind turning to</p> <p>16 Page 5 of Exhibit 1, which is where Schedule A begins,</p> <p>17 and let me know when you are there, please.</p> <p>18 A. Yes, I am.</p> <p>19 Q. Okay. There are five categories -- excuse</p> <p>20 me -- four categories of documents that you have been</p> <p>21 requested to bring with you here today.</p> <p>22 Have you had a chance to review those four</p> <p>23 document requests?</p> <p>24 A. Yes, I have.</p>	<p>1 BY MS. WATSON:</p> <p>2 Q. Doctor, with respect to Exhibit 9A, which</p> <p>3 was one of the invoices you referenced, what is the</p> <p>4 work -- strike that.</p> <p>5 What work is it that you did that is</p> <p>6 reflected in Invoice 9A?</p> <p>7 A. The work that's reflected in 9A -- let me</p> <p>8 make sure the dates, yeah -- the work that's reflected</p> <p>9 in 9A was the work that I did to prepare my general</p> <p>10 report and then also work looking at basically two</p> <p>11 individual cases.</p> <p>12 Q. Okay. And did you separate out your time</p> <p>13 working on the general report versus the time working</p> <p>14 on the two individual cases?</p> <p>15 A. No, I did not.</p> <p>16 Q. And what are the -- what is the total</p> <p>17 hours for that work?</p> <p>18 A. That work was 55.75 hours.</p> <p>19 Q. And did you note the date or dates on</p> <p>20 which you did that work?</p> <p>21 A. I noted in my invoice that it was work</p> <p>22 done from March 31st, 2018, until June 17th, 2018.</p> <p>23 Q. And what are the names of the two</p> <p>24 individual cases?</p>

<p style="text-align: right;">Page 14</p> <p>1 MR. SNELL: You can answer that, to the extent</p> <p>2 you recall.</p> <p>3 BY THE WITNESS:</p> <p>4 A. Yeah, I -- I left those individual records</p> <p>5 elsewhere and I would have to go retrieve them. I</p> <p>6 don't recall the names of those two individual cases.</p> <p>7 BY MS. WATSON:</p> <p>8 Q. Can you estimate out of the 55.75 hours</p> <p>9 that are listed how much of that time was spent</p> <p>10 preparing your general report?</p> <p>11 A. About ten hours.</p> <p>12 Q. So is it safe to say that you began</p> <p>13 drafting your general report in late March of 2018?</p> <p>14 A. I -- I don't recall exactly when I started</p> <p>15 drafting the general report.</p> <p>16 Q. Okay. And then how much did you charge by</p> <p>17 the hour for your work as reflected on that invoice?</p> <p>18 A. I don't state. I believe it's -- I may</p> <p>19 have the math wrong, but I believe it is \$600 per hour</p> <p>20 for records review and opinion in my fee schedule.</p> <p>21 Q. And is there a total dollar amount on that</p> <p>22 invoice?</p> <p>23 A. There is. It's \$33,450, so...</p> <p>24 Q. And let's move onto the second invoice.</p>	<p style="text-align: right;">Page 16</p> <p>1 Well, I -- well, let me restate that.</p> <p>2 From this wave originally four and three that are</p> <p>3 active and on Wave 9, one new case that I've not begun</p> <p>4 work on yet.</p> <p>5 Q. And what is the total dollar amount for</p> <p>6 Invoice 9B?</p> <p>7 A. Invoice 9B was for \$33,450.</p> <p>8 Q. Okay. So that's the exact same dollar</p> <p>9 amount as Invoice 9A?</p> <p>10 A. Oh, oh, oh, I'm sorry. Excuse me. I</p> <p>11 misspoke.</p> <p>12 Q. That's okay.</p> <p>13 A. Gosh, I have to read my own letter</p> <p>14 carefully.</p> <p>15 Invoice 9B was for 28.5 hours for \$17,100,</p> <p>16 and I was commenting that I hadn't received any</p> <p>17 information about my earlier invoice. That's why I</p> <p>18 was mistaken.</p> <p>19 Q. Okay.</p> <p>20 With respect to your general report, have</p> <p>21 you spent any more time aside from the ten hours that</p> <p>22 you referenced earlier drafting your general report?</p> <p>23 A. No, because -- no. No, I have not.</p> <p>24 Q. Have you generated any additional invoices</p>
<p style="text-align: right;">Page 15</p> <p>1 What work did you do to generate that</p> <p>2 invoice?</p> <p>3 A. This was work from July 8th to 30th</p> <p>4 working on review of additional cases.</p> <p>5 Q. And when you say "individual cases," is</p> <p>6 that for purposes of drafting a case-specific report?</p> <p>7 A. I'm sorry. Could you repeat that? We</p> <p>8 lost part of the middle of the question.</p> <p>9 Q. Sure.</p> <p>10 When you say that you were reviewing</p> <p>11 individual cases, was that for purposes of drafting a</p> <p>12 specific causation report for those cases?</p> <p>13 A. Yes, it was.</p> <p>14 Q. Do you know how many individual cases you</p> <p>15 reviewed for purposes of that invoice?</p> <p>16 A. Well, principally one, but also updating</p> <p>17 two others as new information came in on a weekly or</p> <p>18 semimonthly basis.</p> <p>19 Q. So as you sit here today for purposes of</p> <p>20 the Ethicon's litigation, have you been retained to be</p> <p>21 a case-specific expert in a total of three individual</p> <p>22 cases?</p> <p>23 A. I believe originally four and now three</p> <p>24 that are active.</p>	<p style="text-align: right;">Page 17</p> <p>1 with respect to the Ethicon litigation that you</p> <p>2 haven't brought with you today?</p> <p>3 A. No, I have not.</p> <p>4 Q. Have you done any work with respect to the</p> <p>5 Ethicon litigation that you have not yet invoiced for?</p> <p>6 A. Yes, I have.</p> <p>7 Q. Okay. What work is that?</p> <p>8 A. Preparing for this deposition.</p> <p>9 Q. How many hours did you spend preparing for</p> <p>10 this deposition?</p> <p>11 A. Oh, I don't remember exactly, but roughly</p> <p>12 within the last week, I would say that it's probably</p> <p>13 about, about 18 hours re-reviewing materials.</p> <p>14 Q. And did you begin preparing for this</p> <p>15 deposition within the last week?</p> <p>16 A. Well, pretty much, yes.</p> <p>17 Q. And are you -- did you charge \$600 per</p> <p>18 hour for that work?</p> <p>19 A. I have not yet.</p> <p>20 Q. Okay. Will that be your hourly rate?</p> <p>21 A. Yes, it will.</p> <p>22 Q. And what are you charging for your time</p> <p>23 here today?</p> <p>24 A. Oh, my gosh. I'd have to look at my rate</p>

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<p style="text-align: right;">Page 18</p> <p>1 sheet. I think -- I think deposition hourly rate was</p> <p>2 \$750, but I'm not positive.</p> <p>3 Q. Okay.</p> <p>4 Also with Schedule A is consulting</p> <p>5 agreements.</p> <p>6 Do you have any consulting agreements with</p> <p>7 respect to any work you've done with Ethicon?</p> <p>8 A. Not that I'm aware of.</p> <p>9 Q. Have you at any point had consulting</p> <p>10 agreements with Ethicon, whether or not you physically</p> <p>11 have them in your possession or not?</p> <p>12 A. Consulting agreements. I do not recall</p> <p>13 having any consulting agreements with Ethicon.</p> <p>14 Q. Okay. And have you had any correspondence</p> <p>15 or communications with any employees of Ethicon at any</p> <p>16 time?</p> <p>17 A. Yes, I'm sure I have.</p> <p>18 Q. Okay. But none in your possession, is</p> <p>19 that correct?</p> <p>20 A. None that I have on my e-mail or any files</p> <p>21 that I have access to, but I'm sure I've had</p> <p>22 communication with them for various reasons in the</p> <p>23 past.</p> <p>24 Q. Okay. And it's my understanding that you</p>	<p style="text-align: right;">Page 20</p> <p>1 copies of some of the items that are listed on the</p> <p>2 thumb drive that I printed out in the past to be able</p> <p>3 to review.</p> <p>4 BY MS. WATSON:</p> <p>5 Q. And with respect to the paper copies, is</p> <p>6 that of medical literature or something else?</p> <p>7 A. Well, it's largely medical literature but</p> <p>8 also some of the internal documents that Burt's firm</p> <p>9 has provided with -- me from Ethicon and a paper copy</p> <p>10 of my general expert report.</p> <p>11 Q. Okay.</p> <p>12 MS. WATSON: And, Madam Court Reporter, if you</p> <p>13 don't mind just marking those collectively. I think</p> <p>14 we are up to 10 now.</p> <p>15 THE WITNESS: I'm sorry, what was the last thing</p> <p>16 you said?</p> <p>17 THE COURT REPORTER: We're on 11.</p> <p>18 MS. WATSON: Oh, 11. Okay.</p> <p>19 (WHEREUPON, certain documents were</p> <p>20 marked Sand Deposition Exhibit</p> <p>21 No. 11, for identification, as of</p> <p>22 09/26/2018.)</p> <p>23 BY MS. WATSON:</p> <p>24 Q. Dr. Sand, I want to talk a little bit</p>
<p style="text-align: right;">Page 19</p> <p>1 brought an updated CV with you today, which I believe</p> <p>2 is marked as 3B.</p> <p>3 Do you know offhand what the differences</p> <p>4 between 3A, which is the CV that we received with your</p> <p>5 general report, and 3B are?</p> <p>6 A. Well, generally, yes. I went back</p> <p>7 recently on a couple of occasions to try to update my</p> <p>8 publications and to re-sort some of the publications</p> <p>9 and complete citations where there had been electronic</p> <p>10 citations or articles were listed as "in press" but I</p> <p>11 didn't have the complete citation. So just updates</p> <p>12 largely there. My abstract presentations and my</p> <p>13 research grants still remain terribly out of date. I</p> <p>14 just don't have the time to update them.</p> <p>15 Q. And did you bring anything else with you</p> <p>16 today besides the materials we've discussed?</p> <p>17 A. Yes. In front of me I have some of the</p> <p>18 records that I've reviewed and articles.</p> <p>19 MR. SNELL: Counsel, we've already marked the</p> <p>20 thumb drive. Do you mean in addition to that, too?</p> <p>21 MS. WATSON: Yes.</p> <p>22 MR. SNELL: Okay.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Yeah, I just have -- I have some paper</p>	<p style="text-align: right;">Page 21</p> <p>1 about your two reliance lists, your general reliance</p> <p>2 list we've marked as Exhibit 4A and then your</p> <p>3 supplemental general materials list we've marked as</p> <p>4 Exhibit 4B.</p> <p>5 Did you prepare these lists?</p> <p>6 A. I did not.</p> <p>7 Q. Were they provided to you by counsel for</p> <p>8 Ethicon?</p> <p>9 A. They were assembled by them, yes.</p> <p>10 Q. Have you reviewed every document listed on</p> <p>11 Exhibit 4A and 4B?</p> <p>12 A. I have not.</p> <p>13 Q. Okay. How did you choose what materials</p> <p>14 you wanted to review for purposes of drafting your</p> <p>15 general expert report?</p> <p>16 A. Yeah, so a lot of materials, luckily, I've</p> <p>17 read and reviewed in the past over the last 20 some</p> <p>18 odd years, but I specifically did not review the</p> <p>19 company witness depositions. I just realized I didn't</p> <p>20 have time to do that, didn't think they would really</p> <p>21 influence my general report.</p> <p>22 Q. Okay. So the company employee depositions</p> <p>23 do not -- are not a basis for any of your opinions in</p> <p>24 this litigation, is that correct?</p>

<p style="text-align: right;">Page 22</p> <p>1 A. Can you rephrase that?</p> <p>2 Q. Sure.</p> <p>3 Because you have not reviewed any of the</p> <p>4 Ethicon employee depositions, is it safe to say that</p> <p>5 they are not a basis for your opinions in this</p> <p>6 litigation?</p> <p>7 A. Well, they might be when I have a chance</p> <p>8 to review them in the future, but they certainly have</p> <p>9 not gone into the construction or my thoughts to this</p> <p>10 point as witnessed in my general report.</p> <p>11 Q. Okay. So in forming your opinions in this</p> <p>12 litigation, you didn't find it necessary to request</p> <p>13 certain Ethicon employee depositions, is that correct?</p> <p>14 A. I -- I actually asked for them after I</p> <p>15 reviewed Dr. Rosenzweig's report, but I didn't have</p> <p>16 time to review them prior to preparing my general</p> <p>17 report.</p> <p>18 Q. And why did you ask for them after</p> <p>19 reviewing Dr. Rosenzweig's deposition?</p> <p>20 A. Well, once I reviewed --</p> <p>21 MR. SNELL: Hold on.</p> <p>22 Counsel, I think you made a misstatement.</p> <p>23 You said his deposition. The doctor testified that he</p> <p>24 reviewed Dr. Rosenzweig's report.</p>	<p style="text-align: right;">Page 24</p> <p>1 I hope to be able to read them in the future and</p> <p>2 augment my opinion going forward.</p> <p>3 Q. But were those depositions available to</p> <p>4 you prior to this deposition here today?</p> <p>5 A. Yes, they were and are.</p> <p>6 Q. Okay. Have you reviewed or attended any</p> <p>7 trials against Ethicon?</p> <p>8 A. Have I reviewed or attended any trials</p> <p>9 against Ethicon? Well, I've reviewed the materials in</p> <p>10 the three cases that have been brought, but I</p> <p>11 certainly have not attended any trials and I've</p> <p>12 reviewed opinions expressed by your experts -- some of</p> <p>13 your experts.</p> <p>14 Q. Okay. When you said you reviewed the</p> <p>15 materials with respect to the trials, have you</p> <p>16 reviewed trial transcripts?</p> <p>17 A. No, I don't believe I have reviewed trial</p> <p>18 transcripts.</p> <p>19 Q. You mentioned that you've reviewed</p> <p>20 Dr. Rosenzweig's report. What other materials have</p> <p>21 you reviewed with respect to Plaintiffs' experts in</p> <p>22 the Ethicon litigation?</p> <p>23 MR. SNELL: Object; form.</p> <p>24 Go ahead.</p>
<p style="text-align: right;">Page 23</p> <p>1 MS. WATSON: Understood. Thanks, Burt. Yeah,</p> <p>2 I'll rephrase that.</p> <p>3 BY MS. WATSON:</p> <p>4 Q. Doctor, why did you request the</p> <p>5 depositions of Ethicon employees after reading</p> <p>6 Dr. Rosenzweig's report?</p> <p>7 A. Well, because I realized that Bruce had --</p> <p>8 was referring to a lot of information I wasn't aware</p> <p>9 of, internal documents from Ethicon as well as some</p> <p>10 information from these depositions, and so I was</p> <p>11 asking where did this come from and I need to have</p> <p>12 this information to review. I just didn't have time</p> <p>13 to review all of the information.</p> <p>14 Q. So is it safe to say that as you sit here</p> <p>15 today you -- you haven't had an opportunity to review</p> <p>16 all of the materials necessary to offer complete and</p> <p>17 full opinions in this litigation?</p> <p>18 A. I think that might be a</p> <p>19 mischaracterization. I do not know all of the</p> <p>20 contents of the company witness depositions. I would</p> <p>21 imagine that there is probably information there that</p> <p>22 would augment my opinions and general report in the</p> <p>23 future, but I don't know what's in those depositions</p> <p>24 currently, so I can't really comment beyond that, but</p>	<p style="text-align: right;">Page 25</p> <p>1 BY THE WITNESS:</p> <p>2 A. Yeah, I mean, that's somewhat extensive.</p> <p>3 It is certainly covered in all of the materials that</p> <p>4 have been submitted that I have reviewed on the thumb</p> <p>5 drive.</p> <p>6 BY MS. WATSON:</p> <p>7 Q. Okay. So if a Plaintiff's expert report</p> <p>8 or deposition is on the thumb drive, is it safe to</p> <p>9 assume that you have reviewed it in full?</p> <p>10 A. I have -- I have reviewed them, some in</p> <p>11 greater detail than others.</p> <p>12 Q. And you mentioned reviewing</p> <p>13 Dr. Rosenzweig's report.</p> <p>14 Do you recall any other expert reports</p> <p>15 from the Plaintiffs' side that you have reviewed?</p> <p>16 A. Dr. Blaivas's report. I don't want to</p> <p>17 confuse what I've done here for Ethicon and what I've</p> <p>18 done elsewhere outside. It's been a while.</p> <p>19 Q. Do you recall whether you've reviewed any</p> <p>20 depositions of any Plaintiffs' experts in the Ethicon</p> <p>21 litigation?</p> <p>22 A. Yes, I have.</p> <p>23 Q. Which depositions do you recall reviewing?</p> <p>24 A. As I sit here now, not remembering</p>

<p style="text-align: right;">Page 26</p> <p>1 opinions versus their depositions to answer that</p> <p>2 question adequately -- accurately.</p> <p>3 Q. Do you know Dr. Rosenzweig personally?</p> <p>4 A. I do.</p> <p>5 Q. And do you respect him as a physician?</p> <p>6 A. Respect him as a physician, that's a</p> <p>7 difficult question when it comes to Bruce.</p> <p>8 Q. Well, can you answer it?</p> <p>9 A. Sure.</p> <p>10 Bruce and I were friends. When Bruce was</p> <p>11 in training, first came to Chicago in practice, I</p> <p>12 think he is a very bright individual, but I certainly</p> <p>13 have been disappointed that Bruce chose to -- had told</p> <p>14 me years ago that he really didn't enjoy practicing</p> <p>15 medicine shortly before he left the practice of</p> <p>16 medicine and retired from medicine to go off to ski</p> <p>17 and film and do other things outside of medicine that</p> <p>18 he thought he could afford financially. And now I</p> <p>19 know Bruce has been back in practice at Rush for a</p> <p>20 number of years and -- and doing this work, acting as</p> <p>21 a Plaintiff's expert in mesh litigation, and I can't</p> <p>22 say that I necessarily respect everything that Bruce</p> <p>23 has done in his work since he's been back, sadly.</p> <p>24 Q. Okay. You mentioned that you brought with</p>	<p style="text-align: right;">Page 28</p> <p>1 any of those today?</p> <p>2 A. If you are referring --</p> <p>3 MR. SNELL: Objection; asked and answered.</p> <p>4 MS. WATSON: Well, I don't think the doctor and</p> <p>5 I are on the same page. He referenced</p> <p>6 Dr. Rosenzweig's report which I don't think is an</p> <p>7 internal Ethicon document.</p> <p>8 MR. SNELL: No, I think that misstates his</p> <p>9 testimony. He has here and we have marked internal</p> <p>10 Ethicon documents that he testified that he has</p> <p>11 because Dr. Rosenzweig has referenced them in his</p> <p>12 report that he has seen.</p> <p>13 MS. WATSON: Oh, okay.</p> <p>14 MR. SNELL: That was what he was testifying to.</p> <p>15 I don't know if that's how you took it, but he --</p> <p>16 MS. WATSON: Yeah, I didn't understand that.</p> <p>17 MR. SNELL: I can short-circuit this, because</p> <p>18 you are not here, and tell you, on the thumb drive,</p> <p>19 for example, when we sent him Dr. Rosenzweig's report</p> <p>20 back in March, we included all of the materials and</p> <p>21 company documents and literature that Dr. Rosenzweig</p> <p>22 cited. So --</p> <p>23 MS. WATSON: Okay.</p> <p>24 MR. SNELL: He has some of those in hard copy</p>
<p style="text-align: right;">Page 27</p> <p>1 you today some internal Ethicon documents.</p> <p>2 How did you select which documents you</p> <p>3 were going to bring with you here today?</p> <p>4 A. Sort of by default. Butler Snow sent me a</p> <p>5 binder of key documents and so I had them in paper</p> <p>6 form from them and I just happened to have them with</p> <p>7 me today and there was some items that I thought might</p> <p>8 come up in the deposition that I wanted to have them</p> <p>9 here in paper form.</p> <p>10 Q. Okay. Did you bring the binder with you</p> <p>11 today?</p> <p>12 A. All of the materials are present in front</p> <p>13 of me.</p> <p>14 Q. Okay. And with respect to the items that</p> <p>15 you thought might come up, what are those items?</p> <p>16 A. Oh, well, trying to address specific items</p> <p>17 and specifically Dr. Rosenzweig's opinions.</p> <p>18 Q. With respect to the internal Ethicon</p> <p>19 documents, did you bring any of those that you thought</p> <p>20 might be addressed today?</p> <p>21 A. That was what I was just saying, yes.</p> <p>22 Q. Okay. Do you understand -- and maybe I'm</p> <p>23 not being clear, but when I say "internal Ethicon</p> <p>24 documents," I mean corporate documents, did you bring</p>	<p style="text-align: right;">Page 29</p> <p>1 here that he brought, but because you can't see the</p> <p>2 thumb drive, there is literally a -- probably a folder</p> <p>3 or a file that says "Rosenzweig" that's got his report</p> <p>4 and all of the company documents that Dr. Rosenzweig</p> <p>5 cites to.</p> <p>6 MS. WATSON: Understood. That makes sense. I</p> <p>7 was -- I was the one who was confused.</p> <p>8 BY MS. WATSON:</p> <p>9 Q. Okay, Doctor, aside from Dr. Rosenzweig's</p> <p>10 report and internal documents that he may have relied</p> <p>11 on, have you brought any other internal corporate</p> <p>12 documents with you here today aside from the thumb</p> <p>13 drive, anything in hard copy?</p> <p>14 A. No, I don't believe so.</p> <p>15 Q. Okay. Have you, outside of</p> <p>16 Dr. Rosenzweig's internal documents that he relied on,</p> <p>17 have you reviewed any internal documents from Ethicon?</p> <p>18 A. No, I don't -- well, yes.</p> <p>19 Q. Okay. What documents have you reviewed</p> <p>20 aside from Dr. Rosenzweig's reliance materials?</p> <p>21 A. Oh, my. You know, that -- that's a pretty</p> <p>22 broad, extensive list of different memos and I can't,</p> <p>23 as I sit here today, I'm not sure that I can remember</p> <p>24 and segregate which ones Bruce has talked about in his</p>

<p style="text-align: right;">Page 30</p> <p>1 report versus which ones he hasn't, but -- oh, gosh, 2 this is so hard, I wish you were here, I could just 3 show you the page. 4 Do you want me to read the list? I don't 5 know if you want to spend your time that way. 6 Q. Do you have a list of the documents 7 that -- the internal Ethicon documents that you've 8 reviewed that are separate and apart from the ones 9 listed in Dr. Rosenzweig's report and reliance list? 10 A. I do not, that's the problem. 11 Q. Okay. So as we sit here today with 12 respect to your own reliance list, you don't -- you 13 can't identify which internal documents that are 14 listed on your reliance list that you have reviewed 15 versus you haven't reviewed, is that correct? 16 A. No, that's not. 17 MR. SNELL: Objection; I think that misstates, 18 Counsel. 19 BY THE WITNESS: 20 A. That's not what I'm saying. 21 BY MS. WATSON: 22 Q. Okay. Well, I thought you testified 23 earlier that you have not reviewed every document 24 that's listed on your reliance list, is that correct?</p>	<p style="text-align: right;">Page 32</p> <p>1 them and read some sections in entirety, but, yes, 2 clearly others I just briefly glanced at and said 3 that's not relevant to where I want to go with my 4 general report and opinions. 5 Q. With respect to the internal Ethicon 6 documents, did you request those or were they just 7 presented to you by defense counsel? 8 A. As I stated, my original request was, once 9 I read Bruce's report, was to ask for everything that 10 he had referenced and all of that information and 11 anything else that Mr. Snell thought would be relevant 12 to these claims and would help me formulate my 13 opinion. 14 Q. Prior to reviewing Dr. Rosenzweig's 15 report, did you receive from Ethicon's lawyers any 16 internal Ethicon documents? 17 A. I do not believe so prior to reading 18 Dr. Rosenzweig's report. 19 Q. Have you reviewed any of Ethicon's design 20 specifications for any of its products? 21 A. Gee, I'm not sure I understand what design 22 specifications would be relative to what I read about. 23 I have read a lot of documents about the development 24 of different products and modification of different</p>
<p style="text-align: right;">Page 31</p> <p>1 A. Yes, and I specifically stated that I 2 hadn't reviewed the company witness depositions, as we 3 discussed earlier. 4 Q. Okay. There are a number of materials 5 listed in your reliance list that are internal Ethicon 6 documents that are not depositions. 7 Have you reviewed all of those internal 8 Ethicon documents listed in your reliance list? 9 A. I have gone through them, thumbed through 10 them and reviewed some in some detail and the others 11 just very cursory. 12 Q. Okay. Is it your testimony that you have 13 reviewed in some form or fashion every internal 14 Ethicon document listed in your reliance list? 15 A. That's probably a misstatement. 16 Q. Okay. So there are some that you may not 17 have reviewed at all, is that correct? 18 A. Right. So I went through these documents 19 that you see listed on the thumb drive with the 20 exception of the depositions and very quickly went 21 through many, many of them that I did not think would 22 be relevant to me forming a general report. Others I 23 thought were relevant and I stopped to take the time 24 and read them in entirety or scanned through part of</p>	<p style="text-align: right;">Page 33</p> <p>1 products and review of different products. So within 2 there you have -- within those documents, I'm sure, 3 things that you would consider under that heading, but 4 I couldn't segregate what specifically you intend by 5 that question. 6 Q. Okay. Is it safe to say that you are not 7 holding yourself out as an expert in product design? 8 MR. SNELL: Objection; form, misstates. 9 BY THE WITNESS: 10 A. Well, I think -- I think I have expertise 11 in product design having developed products myself, 12 worked with numerous companies in the past on 13 developing products, bringing them to market, revising 14 them. So, yes, I think I have expertise in that 15 arena. 16 BY MS. WATSON: 17 Q. All right. What products have you 18 participated in the design of? 19 A. Well, I have myself worked on original art 20 and product design for a -- two prolapse procedures 21 and worked on -- which never were accepted, bore 22 fruit. I have worked on product design and 23 development and refinement of the Capio device with 24 Boston Scientific and the Capio CL device,</p>

<p style="text-align: right;">Page 34</p> <p>1 specifically. I have worked on the revisions to</p> <p>2 product design on a radio frequency coagulation device</p> <p>3 with Novasys, and then I've worked with a number of</p> <p>4 different companies on their FDA submissions for their</p> <p>5 new products and revising those products to meet FDA's</p> <p>6 standards.</p> <p>7 Q. Okay.</p> <p>8 MR. SNELL: Hold on one second, Counsel.</p> <p>9 MS. WATSON: I'm sorry. Were you done?</p> <p>10 MR. SNELL: I don't know if he was done because</p> <p>11 I think he is still thinking over here.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Well, I didn't know if you wanted to know</p> <p>14 specifically those products where I didn't design them</p> <p>15 or work on revising the design but helped prepare them</p> <p>16 for FDA submission.</p> <p>17 BY MS. WATSON:</p> <p>18 Q. I appreciate that, and I'll just ask some</p> <p>19 follow-up questions. I just wanted to make sure that</p> <p>20 you were done with your answer.</p> <p>21 MR. SNELL: Are you done or are there more</p> <p>22 design experience?</p> <p>23 BY THE WITNESS:</p> <p>24 A. As far as I can recall, I'm done.</p>	<p style="text-align: right;">Page 36</p> <p>1 Q. Okay. With respect to the Prolift-related</p> <p>2 products.</p> <p>3 A. Prolift? I'm sorry.</p> <p>4 Q. The polypropylene mesh products.</p> <p>5 A. Okay.</p> <p>6 MR. SNELL: Objection.</p> <p>7 BY THE WITNESS:</p> <p>8 A. I have not been involved in -- well, go</p> <p>9 ahead. I'm sorry. You ask your question.</p> <p>10 BY MS. WATSON:</p> <p>11 Q. Well, I thought you mentioned that -- what</p> <p>12 I wrote down was they were quote/unquote novel new</p> <p>13 devices to treat prolapse and maybe I have misquoted</p> <p>14 you there.</p> <p>15 A. Correct. No, they were novel products to</p> <p>16 treat prolapse. When you were talking, it came out as</p> <p>17 "Prolift."</p> <p>18 MR. SNELL: That's what I heard, too, "Prolift."</p> <p>19 I don't know what the court reporter heard. That was</p> <p>20 my objection.</p> <p>21 MS. WATSON: Okay. Understood.</p> <p>22 BY MS. WATSON:</p> <p>23 Q. No, were they polypropylene mesh devices?</p> <p>24 A. No, they were not.</p>
<p style="text-align: right;">Page 35</p> <p>1 BY MS. WATSON:</p> <p>2 Q. Okay.</p> <p>3 Doctor, at the beginning of your answer</p> <p>4 you've referenced that you helped in the design of</p> <p>5 prolapse procedures, and I'm a little confused by that</p> <p>6 answer.</p> <p>7 Were you involved in the development of</p> <p>8 procedures or some sort of medical device to treat</p> <p>9 prolapse?</p> <p>10 A. Yeah. So, there were two instances where</p> <p>11 I developed original artwork and novel new devices --</p> <p>12 actually, I just thought of another. Yeah, novel new</p> <p>13 devices that I was pitching to two different</p> <p>14 corporations in hopes that they would accept those and</p> <p>15 out license them and bring those products forward to</p> <p>16 market. Both were rejected.</p> <p>17 And -- and then I also forgot another</p> <p>18 product that I helped Boston Scientific with. It was</p> <p>19 a finger-loaded push-and-catch suturing device that</p> <p>20 Dr. Levy had developed and was trying to bring forward</p> <p>21 for Boston Scientific, and I worked with he and them</p> <p>22 on modifying that product and making changes to that</p> <p>23 product. But, again, that product also, they did not</p> <p>24 purchase that product in the end.</p>	<p style="text-align: right;">Page 37</p> <p>1 Q. What kinds of devices were they? Can you</p> <p>2 just generally describe them?</p> <p>3 A. Yeah. In both instances they were novel</p> <p>4 products for the application of anchoring biologic</p> <p>5 grafts for prolapse surgery and ways to develop the</p> <p>6 grafts, template the grafts to make them easier to</p> <p>7 apply in a kit form.</p> <p>8 Q. And over what years were you working on</p> <p>9 those devices?</p> <p>10 A. Certainly as I sit here today I cannot</p> <p>11 recall exactly. I'd have to go pull files out of my</p> <p>12 basement to look, but roughly I think, with Boston</p> <p>13 Scientific, those ideas were pitched back in the early</p> <p>14 2000s period, probably before 2005, and with Coloplast</p> <p>15 more recently probably back to somewhere around 2009,</p> <p>16 2010, I would guess.</p> <p>17 Q. And then with respect to the FDA</p> <p>18 submissions that you assisted with, what companies did</p> <p>19 you consult with with respect to that work?</p> <p>20 A. FDA submissions for product or a product</p> <p>21 and drug?</p> <p>22 Q. Let's do product first, please.</p> <p>23 A. Okay. For product, oh, gee, it goes back</p> <p>24 advising EMPI on a pelvic floor electrical stimulator</p>

<p style="text-align: right;">Page 38</p> <p>1 many, many, many years ago, and Hollister on 2 modifications of a French stimulator for introduction 3 into the US of electrical stimulators. 4 Gee, I'm forgetting which agency, but I 5 was asked years ago before 1991 to review a Polish 6 electrical stimulator and it was by the US -- a branch 7 of the U.S. Government, I can't remember, and I was 8 reviewing that product to assess its safety during the 9 FDA process. So I wasn't working for the company. I 10 was a reviewer, I guess, for -- I don't think it was 11 the FDA directly, but some branch that was working 12 with the FDA as they reviewed the product. 13 And then I have worked with, as I 14 mentioned, Novasys in their FDA submission and 15 revision of their product. And currently I am next 16 week testifying before the FDA with Amphora for their 17 radiofrequency coagulation device for the treatment of 18 detrusor overactivity and overactive bladder syndrome. 19 Device, device, device. And I've worked 20 with Valencia Technologies on their development, FDA 21 submission, and research program and publication 22 strategy for their eCoin device and their interactions 23 with FDA and helped them with their submission and 24 their subsequent application issues. And, actually, I</p>	<p style="text-align: right;">Page 40</p> <p>1 with regard to that question. 2 THE WITNESS: Thank you. 3 BY THE WITNESS: 4 A. I've had consulting agreements in the past 5 with Boston Scientific, I've had consulting agreements 6 in the past with Coloplast, I've had consulting 7 agreements in the past with AMS. 8 BY MS. WATSON: 9 Q. Have any of those consulting agreements 10 been with respect to transvaginal mesh products? 11 A. Well, yes, I have acted as a general 12 consultant to those companies during the period of 13 time where they were developing their midurethral 14 sling products and also during the time where some of 15 them were bringing forward mesh kits for the treatment 16 of genital prolapse. 17 Q. Were you paid for your work as a 18 consultant for those companies? 19 A. Yes, I was paid for my work as a 20 consultant for those companies. 21 Q. Do you recall how much you were paid? 22 A. I don't, actually, and oftentimes I was 23 paid on a per activity -- well, oftentimes. I think I 24 was always paid on a per activity basis.</p>
<p style="text-align: right;">Page 39</p> <p>1 think there are a few more or a couple of more and I 2 just am not recalling right now. 3 Q. Have you been involved in the design of 4 any transvaginal mesh products? 5 A. I do not believe that I've been involved 6 in the design of any transvaginal mesh products, but 7 I've certainly acted as a medical expert to comment on 8 these products and their clinical evaluation. 9 Q. Have you been involved in the FDA 10 submission for any transvaginal mesh products? 11 A. I have not. 12 Q. And I believe you said that you don't 13 think you've ever had any consulting agreements with 14 Ethicon. 15 Have you had any consulting agreements 16 with any other transvaginal mesh manufacturer? 17 A. Yes, I have. 18 Q. Who have you had consulting agreements 19 with? 20 MR. SNELL: I, again, just want to caution the 21 doctor to the extent something is confidential, you 22 should not disclose that. I'm not a lawyer for any of 23 those companies and I can't protect the 24 confidentiality, but I leave it up to you, Doctor,</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. Do you recall when you first started 2 working as a consultant with respect to transvaginal 3 mesh for any of those three companies? 4 A. Yeah, I don't think I ever worked 5 specifically as a consultant for any of those 6 companies for transvaginal mesh per se. They 7 certainly, while I was acting as a consultant for them 8 they have asked me for my opinions and clinical review 9 of some of their products, but ostensibly I was not 10 hired as an expert for their transvaginal mesh 11 prolapse products, but certainly I acted as a 12 consultant with those companies for their development 13 programs and marketing programs for their midurethral 14 slings. 15 Q. Okay. And when did that -- that work 16 begin, what year approximately? 17 A. Oh, my. Well, it was different for 18 different companies. 19 So, for Boston Scientific, that was first, 20 and I was working with them while they were 21 introducing the Vesica, their first bone-anchored 22 sling, and then the various modifications that we 23 worked on subsequent to that, and then the Capio CL 24 transvaginal sling project that I worked on a lot.</p>

<p style="text-align: right;">Page 42</p> <p>1 And so I think the time course for that was probably 2 around, oh, maybe 1988, '89 through maybe 2002, 2003, 3 somewhere in that timeframe is my best guess. 4 My work with AMS was, of course, later 5 than that as their products evolved a little bit later 6 than that, so more around the introduction of SPARC 7 and Monarch, and my best guess is those products were 8 being launched in 2001 to -- well, the early 2000s, 9 I'll say. 10 And then for Coloplast briefly, and much 11 later, probably somewhere around 2010, maybe, for a 12 year or two. 13 Q. Okay. With respect to AMS, you said you 14 started your work in the early 2000s. 15 When did you stop working with AMS? 16 A. Oh, working for AMS, you know, I don't 17 recall exactly. Rough guess would probably be around 18 2010, but I don't have much confidence in my timeline 19 there. 20 Q. With respect to any of those three 21 companies, did you ever have an annual contract with 22 them? 23 A. I don't think -- well, I don't know that. 24 I don't know.</p>	<p style="text-align: right;">Page 44</p> <p>1 BY MS. WATSON: 2 Q. Okay. Same question for AMS, do you think 3 it was over \$500,000? 4 A. Oh, nowhere near that number. 5 Q. Okay. What about 100,000? 6 MR. SNELL: Same objection. Go ahead. 7 BY THE WITNESS: 8 A. I am confident that I made nowhere near 9 that number for AMS -- from AMS, excuse me. 10 BY MS. WATSON: 11 Q. What about Boston Scientific? 12 A. For Boston Scientific over a number of 13 years during numerous labs, numerous lectures, 14 consulting for them, it might be around that number, 15 roughly. 16 Q. Okay. And that's for AMS? 17 A. No. That is for Boston Scientific. I 18 stated earlier for AMS nowhere near that number. 19 Q. Okay. Have you served as a preceptor for 20 any transvaginal mesh manufacturer? 21 A. Yes, I have. 22 Q. Manufacturer? 23 MR. SNELL: Objection; asked and answered. He 24 testified he did. I don't know if you caught that.</p>
<p style="text-align: right;">Page 43</p> <p>1 Q. With respect -- I know I asked you earlier 2 how much you think you made as a consultant for those 3 three companies and you said you didn't know, but can 4 you give me any sort of estimate? 5 MR. SNELL: You're not -- you're not here to 6 guess, I'll just give you that caution. 7 BY THE WITNESS: 8 A. Yeah, to Burt's point, I mean, it would 9 just be a guess. I really don't know. In the case of 10 Coloplast, I know that it was probably little. You 11 know, I think I went to two advisory board meetings 12 for them maybe over the course of two years. So maybe 13 \$5,000 or less. 14 For AMS and certainly for Boston 15 Scientific where I did a lot more work than for the 16 other two companies, I really couldn't guess. 17 Q. Do you think for Boston Scientific you 18 made in total over \$500,000? 19 A. Oh, gosh, no. 20 MR. SNELL: Hold on. 21 I'm sorry. Object to form. 22 Go ahead. 23 BY THE WITNESS: 24 A. Oh, gosh, no.</p>	<p style="text-align: right;">Page 45</p> <p>1 BY MS. WATSON: 2 Q. So I said which manufacturers? 3 A. Oh, we didn't hear the -- we just heard 4 "manufacturer." Sorry. 5 Which manufacturer. I act as a preceptor 6 for Boston Scientific training people how to do 7 bone-anchored midurethral slings, vaginal wall slings, 8 sacrospinous vaginal vault suspensions and Capiro CL 9 slings. I probably, I think, that to a very limited 10 degree I may have precepted people for AMS on how to 11 do Monarch procedures, their transobturator 12 midurethral sling, but I'm not real confident if that 13 happened just once or a few times. 14 Q. And are you -- and maybe you said this and 15 I just didn't understand. 16 Are you currently a preceptor for Boston 17 Scientific? 18 A. I -- I am not currently a consultant nor a 19 preceptor for any of those companies. 20 Q. Okay. And then with respect to the Boston 21 Scientific products, which -- I know you mentioned 22 bone-anchored midurethral slings and the Capiro, but 23 can you be more specific as to the actual product 24 aside from the Capiro that you've preceptored on?</p>

<p style="text-align: right;">Page 46</p> <p>1 A. Well, those are the products, so the</p> <p>2 Boston Scientific products that I was teaching people</p> <p>3 to use, ostensibly, were the Capio device and the</p> <p>4 Capio CL device, using those devices to do</p> <p>5 sacrospinous vaginal vault suspensions and bladder</p> <p>6 neck slings, rectus fascia and autologous fascial</p> <p>7 slings at the bladder neck.</p> <p>8 Q. Okay. So -- well, strike that.</p> <p>9 And then, aside from doing preceptorships,</p> <p>10 have you taught any professional education programs</p> <p>11 for any transvaginal mesh manufacturers?</p> <p>12 A. I recently learned in a deposition that,</p> <p>13 evidently for Boston Scientific, that I had when I was</p> <p>14 teaching at cadaver courses, that I may have, I still</p> <p>15 don't recall this, but I may have taught people how to</p> <p>16 use some of their mesh products or a mesh product.</p> <p>17 Q. Okay. And I'm sorry. Did you say that</p> <p>18 was for Boston Scientific or AMS?</p> <p>19 A. I said that was for Boston Scientific.</p> <p>20 Q. And do you think that was just one course</p> <p>21 or a number of courses?</p> <p>22 A. I have to believe that it was just one</p> <p>23 course.</p> <p>24 Q. And do you recall what products would have</p>	<p style="text-align: right;">Page 48</p> <p>1 it was that I was not using those products in my</p> <p>2 clinical practice.</p> <p>3 Q. Why weren't you using them in your</p> <p>4 clinical practice?</p> <p>5 A. I was much more interested in using</p> <p>6 biologic regenerative grafts in my clinical practice</p> <p>7 along with native tissue surgery at the time.</p> <p>8 Q. And when you say "at the time," is that, I</p> <p>9 just lost my -- was that in the 2000s, early 2000s?</p> <p>10 A. That was when those products were first</p> <p>11 being introduced, yes.</p> <p>12 Q. And when did you first start using</p> <p>13 polypropylene mesh products to treat stress urinary</p> <p>14 incontinence?</p> <p>15 MR. SNELL: Object to form.</p> <p>16 Go ahead.</p> <p>17 BY THE WITNESS:</p> <p>18 A. I first did my first TVT procedures in</p> <p>19 1999.</p> <p>20 BY MS. WATSON:</p> <p>21 Q. And why is it, then, that you were more</p> <p>22 interested in the biologic products when you were</p> <p>23 working with AMS and Boston Scientific?</p> <p>24 A. Why was it? Well, for a couple of</p>
<p style="text-align: right;">Page 47</p> <p>1 been covered?</p> <p>2 A. I don't.</p> <p>3 Q. That was not a memorable experience, I</p> <p>4 guess?</p> <p>5 A. Well, I -- the problem is I didn't think I</p> <p>6 had -- had done that at all.</p> <p>7 Q. Okay.</p> <p>8 A. And -- but evidently I was teaching at a</p> <p>9 course at the same time that that product was being</p> <p>10 introduced and taught to participants, so I could not</p> <p>11 deny that I maybe hadn't shown people how to anchor</p> <p>12 the mesh, but I don't have any independent</p> <p>13 recollection of that, actually, to be fair.</p> <p>14 And my -- my involvement with all three of</p> <p>15 these companies in teaching products when I was their</p> <p>16 paid instructor or preceptor really centered around</p> <p>17 their anti-incontinence operations, with the exception</p> <p>18 of using the Capio device for reconstructive surgery,</p> <p>19 but not with plastic mesh or polypropylene mesh.</p> <p>20 Q. Okay. And is there a reason why you</p> <p>21 didn't train doctors in terms as a preceptor with</p> <p>22 respect to the polypropylene mesh products?</p> <p>23 A. I presume, I really can't speak for Boston</p> <p>24 Scientific, AMS and Coloplast, but I presume because</p>	<p style="text-align: right;">Page 49</p> <p>1 reasons. One, I thought that they could add benefit</p> <p>2 with little or hopefully no risk at the time then, and</p> <p>3 no risk, I would say, essentially at the time now to</p> <p>4 speak of. And also because I was hoping that they</p> <p>5 could work as carriers for gene therapy and the</p> <p>6 addition of other factors to the graft to improve</p> <p>7 wound healing. I was doing basic science research at</p> <p>8 the time on wound healing and plasma transfection of</p> <p>9 individual's tissues, et cetera, using the New Zealand</p> <p>10 white rabbit to improve wound healing.</p> <p>11 So I was looking at polypropylene mesh in</p> <p>12 that introduction as a step forward for the science,</p> <p>13 but I was more interested in trying to leapfrog ahead,</p> <p>14 generations ahead to products that we could use safely</p> <p>15 and more effectively in the future.</p> <p>16 Q. In your current practice, do you still use</p> <p>17 biologic and autologous slings to treat stress urinary</p> <p>18 incontinence in women?</p> <p>19 A. Well, I was talking more about prolapse</p> <p>20 just now when I was talking about biologic products</p> <p>21 and not for the treatment of stress urinary</p> <p>22 incontinence, but, yes, now I, as I have forever,</p> <p>23 sometimes do rectus -- well, usually rectus fascia</p> <p>24 midureth- -- no, not midurethral slings -- rectus</p>

<p style="text-align: right;">Page 50</p> <p>1 fascia bladder neck slings not infrequently, and also</p> <p>2 in the past I've used fascia lata bladder neck slings.</p> <p>3 I really haven't done that for a number of years just</p> <p>4 for some practical reasons. But, yes, I also now use</p> <p>5 polypropylene mesh also for reconstructive surgical</p> <p>6 procedures.</p> <p>7 Q. Okay. Are there risks associated with</p> <p>8 polypropylene mesh slings that are not present with</p> <p>9 respect to biologic slings?</p> <p>10 A. Are there risks -- well, the risks are</p> <p>11 different. Categorically the risks are sort of the</p> <p>12 same. We have problems with both polypropylene mesh</p> <p>13 midurethral slings as well as rectus fascia and fascia</p> <p>14 lata bladder neck slings with urinary retention,</p> <p>15 infections, pain, dyspareunia, exposure of the mesh,</p> <p>16 abscess formation. The risks, essentially, are</p> <p>17 similar. The prevalence of risks in different buckets</p> <p>18 are different to some degree.</p> <p>19 MS. WATSON: Burt, do you want to take a break?</p> <p>20 We've been going about an hour and ten minutes.</p> <p>21 MR. SNELL: Yes. I think that's a good idea. I</p> <p>22 have to use the restroom.</p> <p>23 MS. WATSON: I do, too.</p> <p>24 MR. SNELL: I just want to make a statement,</p>	<p style="text-align: right;">Page 52</p> <p>1 MR. SNELL: Well, I don't want that question to</p> <p>2 stand about being about biologics and he is testifying</p> <p>3 about the rectus -- autologous rectus fascia sling,</p> <p>4 so...</p> <p>5 MS. WATSON: Then maybe, Burt, I think maybe it</p> <p>6 would be better if you just clean it up --</p> <p>7 MR. SNELL: Okay.</p> <p>8 MS. WATSON: -- like you said, on -- on</p> <p>9 redirect.</p> <p>10 MR. SNELL: All right. So --</p> <p>11 THE WITNESS: Sorry to be nonresponsive. I</p> <p>12 misunderstood, yeah.</p> <p>13 MR. SNELL: It's okay. So I'm going to move to</p> <p>14 strike then the last answer as nonresponsive to the</p> <p>15 question regarding biologic slings.</p> <p>16 MS. WATSON: Okay. Okay. Break time.</p> <p>17 MR. SNELL: Yes, good break time.</p> <p>18 (WHEREUPON, a recess was had</p> <p>19 from 10:12 to 10:23 a.m.)</p> <p>20 BY MS. WATSON:</p> <p>21 Q. Okay. Doctor, we are back on the record</p> <p>22 after a short break, and I want to switch the gears</p> <p>23 slightly.</p> <p>24 Have you done any work at this time,</p>
<p style="text-align: right;">Page 51</p> <p>1 too, on the record, Diane, just so you are -- and you</p> <p>2 probably picked up on this too, at least in his last</p> <p>3 answer, I almost moved to strike it as nonresponsive.</p> <p>4 I thought your question -- was your</p> <p>5 question about biologic or -- because your -- the</p> <p>6 witness' answer was about autologous fascia and rectus</p> <p>7 fascia. There is --</p> <p>8 THE WITNESS: Oh, yeah.</p> <p>9 MR. SNELL: There is an issue there that -- that</p> <p>10 I may have to clean up on on my redirect, but I didn't</p> <p>11 want you to think that I talked to him about it</p> <p>12 outside of your presence because I don't know if there</p> <p>13 was a communication issue there, but anyway.</p> <p>14 THE WITNESS: Well, should we clear it up before</p> <p>15 the break is taken?</p> <p>16 MR. SNELL: Do you want to do that, Diane,</p> <p>17 because otherwise I'm going to need to move to strike?</p> <p>18 MS. WATSON: That's fine. Do you want to clear</p> <p>19 it up now?</p> <p>20 MR. SNELL: Yeah, why don't we do it now,</p> <p>21 because I am -- we can have the court reporter read</p> <p>22 the question back.</p> <p>23 MS. WATSON: Or I can ask a different question,</p> <p>24 if you prefer.</p>	<p style="text-align: right;">Page 53</p> <p>1 outside of the (inaudible) that you are doing for the</p> <p>2 transvaginal mesh litigation?</p> <p>3 (Reporter clarification.)</p> <p>4 BY MS. WATSON:</p> <p>5 Q. Aside from the expert work that you're</p> <p>6 doing for Ethicon with respect to the transvaginal</p> <p>7 mesh litigation, have you done any other work with</p> <p>8 Ethicon?</p> <p>9 MR. SNELL: Object to form.</p> <p>10 Go ahead.</p> <p>11 BY THE WITNESS:</p> <p>12 A. No, I have not done any other work for</p> <p>13 Ethicon.</p> <p>14 BY MS. WATSON:</p> <p>15 Q. And just because counsel for Ethicon</p> <p>16 objected, I'm just going to ask a couple of follow-up</p> <p>17 questions.</p> <p>18 Have you ever been a consultant for</p> <p>19 Ethicon?</p> <p>20 A. I have never been a consultant for</p> <p>21 Ethicon.</p> <p>22 Q. Have you ever been a preceptor for</p> <p>23 Ethicon?</p> <p>24 A. I don't believe I've ever been a preceptor</p>

<p style="text-align: right;">Page 54</p> <p>1 for Ethicon.</p> <p>2 Q. Have you spoken at any professional events</p> <p>3 on behalf of Ethicon?</p> <p>4 A. I don't believe I've spoken at any</p> <p>5 professional events on behalf of Ethicon.</p> <p>6 Q. And have you ever trained -- well, strike</p> <p>7 that.</p> <p>8 Have you attended any courses sponsored by</p> <p>9 Ethicon with respect to transvaginal mesh products?</p> <p>10 A. Does that include TVT when you say</p> <p>11 "transvaginal mesh products"?</p> <p>12 Q. Yes.</p> <p>13 A. Well, yes, I received training in the</p> <p>14 performance of TVT.</p> <p>15 Q. And was that sponsored by Ethicon?</p> <p>16 MR. SNELL: You cut off there.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Was the question was that sponsored by</p> <p>19 Ethicon?</p> <p>20 BY MS. WATSON:</p> <p>21 Q. Was the training you attended with respect</p> <p>22 to the TVT product sponsored by Ethicon?</p> <p>23 A. Yes.</p> <p>24 Q. Do you recall where it was held?</p>	<p style="text-align: right;">Page 56</p> <p>1 use some of the Ethicon's competitors' products.</p> <p>2 Q. What products did you -- did you try?</p> <p>3 A. Well, just about everything, at least in</p> <p>4 small numbers for some and larger numbers for others.</p> <p>5 Q. So what was your -- well, strike that.</p> <p>6 Between 1999 and 2006, did you use any</p> <p>7 transvaginal mesh products to treat stress urinary</p> <p>8 incontinence other than the TVT Retropubic?</p> <p>9 A. Yes, I did.</p> <p>10 Q. What did you use during that time period?</p> <p>11 A. Yeah, and here I get a little fuzzy on</p> <p>12 exact dates, I'm sorry to say, but when Advantage Fit</p> <p>13 was first available, I tried using Advantage Fit.</p> <p>14 Shortly after Bard's crazy upside down/inside out</p> <p>15 midurethral sling was available, I can't remember the</p> <p>16 name, I tried using that in maybe a couple of cases.</p> <p>17 When the transobturator midurethral slings became</p> <p>18 available, thank goodness not ObTape but subsequent to</p> <p>19 ObTape when Monarch became available, I used Monarch.</p> <p>20 And I also believe I had very limited use of Lynx,</p> <p>21 Boston Scientific's top down. And I started using</p> <p>22 SPARCs when the AMS's SPARC product, when it was first</p> <p>23 available for a limited period of time in larger</p> <p>24 numbers.</p>
<p style="text-align: right;">Page 55</p> <p>1 A. I went to Rome to learn to do TVT from a</p> <p>2 friend and colleague there.</p> <p>3 Q. And who is that friend and colleague?</p> <p>4 A. Mauro Cervigni, M-a-u-r-o C-e-r-v-i-g-n-i.</p> <p>5 Q. And have you -- well, strike that.</p> <p>6 You testified earlier that you started</p> <p>7 using the TVT, I believe, in 1999, is that correct?</p> <p>8 A. To the best of my recollection, yes.</p> <p>9 Q. Okay. And do you currently use the TVT</p> <p>10 Retropubic?</p> <p>11 A. Sadly, no, it's not available in our</p> <p>12 institution.</p> <p>13 Q. Could you ask for it to be made available?</p> <p>14 A. Well, I could ask for a lot of things, but</p> <p>15 it's not going to happen.</p> <p>16 Q. When was the last time you implanted a TVT</p> <p>17 retropubic?</p> <p>18 A. I don't know exactly, but I'm -- my</p> <p>19 thoughts are that it probably dates back to around</p> <p>20 2005, 2006.</p> <p>21 Q. And did you -- well, strike that.</p> <p>22 Why did you stop using it in 2006?</p> <p>23 A. I stopped using it because I wanted to try</p> <p>24 some of the competitive products and -- and started to</p>	<p style="text-align: right;">Page 57</p> <p>1 Let's see. I used -- I think this was</p> <p>2 later, but later used the -- oh, this is terrible, I'm</p> <p>3 blocking on the company's name. Oh, Brian, how can I</p> <p>4 forget your company's name.</p> <p>5 Excuse me. It's a company that still is</p> <p>6 marketing midurethral slings and they essentially try</p> <p>7 to copy everyone else's product with reusable handles</p> <p>8 and they sell us, then, the mesh individually, and I</p> <p>9 have used their bottom-up TVT-like midurethral sling</p> <p>10 as well as their transobturator midurethral sling.</p> <p>11 And when the Aris product first became</p> <p>12 available, I started to use that also for</p> <p>13 transobturator midurethral slings.</p> <p>14 Q. Okay. And between the time period of 1999</p> <p>15 and 2006 when you last did a TVT Retropubic, to be</p> <p>16 fair to you, you said 2005 or 2006 is when you</p> <p>17 stopped, when you were --</p> <p>18 A. Yeah, it could have been 2007, too, to be</p> <p>19 fair, but I think it was somewhere roughly around</p> <p>20 there.</p> <p>21 Q. Okay. During that time period, what</p> <p>22 factors played into your decision making with respect</p> <p>23 to which product you were going to use to treat a</p> <p>24 woman with stress urinary incontinence?</p>

<p style="text-align: right;">Page 58</p> <p>1 A. Oh, wow, that's a broad question.</p> <p>2 So a number of different factors then and</p> <p>3 to this day go into my decisions regarding what</p> <p>4 product I'm going to use to treat stress urinary</p> <p>5 incontinence surgically.</p> <p>6 First and foremost, I am a big fan of,</p> <p>7 one, confirming urodynamically that someone has</p> <p>8 urodynamic stress incontinence and, secondarily,</p> <p>9 whether or not they have concomitant detrusor</p> <p>10 overactivity.</p> <p>11 If they have concomitant detrusor</p> <p>12 overactivity, I also want to know whether they have</p> <p>13 high pressure detrusor overactivity; namely, the</p> <p>14 detrusor contractions are greater than 40 centimeters</p> <p>15 of water pressure, and what their detrusor stability</p> <p>16 index is. Are these strong contractions or weak</p> <p>17 contractions occurring at low volumes or high volumes,</p> <p>18 because of our -- my research, our research looking at</p> <p>19 responsiveness of detrusor overactivity in urgency</p> <p>20 urinary incontinence to midurethral slings, bladder</p> <p>21 neck slings, and Burch retropubic urethropexies.</p> <p>22 Then I want to know if someone has a low</p> <p>23 pressure urethra or not, as I described in the</p> <p>24 literature in 1986, and in certain cases whether they</p>	<p style="text-align: right;">Page 60</p> <p>1 going to make some of those individual products.</p> <p>2 Q. Okay. And with respect to how tight</p> <p>3 you're going to make them, what do you mean by that?</p> <p>4 A. Well, for example, if I have a woman who</p> <p>5 is 90 years old, has mild stress urinary incontinence</p> <p>6 and concomitant prolapse and/or potential urodynamic</p> <p>7 stress incontinence and she is a dysfunctional voider,</p> <p>8 she doesn't urinate very well to begin with and has a</p> <p>9 weak little puny detrusor contraction during voiding,</p> <p>10 or even worse, she Valsalva voids in our lab, which</p> <p>11 many people do because it's an unusual experience, I'm</p> <p>12 going to put a retropubic or a transobturator</p> <p>13 midurethral sling or a single incision midurethral</p> <p>14 sling in looser than I normally would to sort of</p> <p>15 compensate for my concerns about her voiding</p> <p>16 efficiency.</p> <p>17 If somebody, on the other hand, has had</p> <p>18 recurrent urodynamic stress incontinence and they have</p> <p>19 poor intrinsic urethral function and I make the</p> <p>20 decision to do a retropubic midurethral sling as</p> <p>21 opposed to a bladder neck sling, based on their</p> <p>22 voiding dysfunction, then if I'm doing a retropubic</p> <p>23 midurethral sling, I'm not really going to do it</p> <p>24 tension-free. I'm going to make it a little bit</p>
<p style="text-align: right;">Page 59</p> <p>1 have an extremely low urethral closure pressure less</p> <p>2 than ten. Nowadays we also look at their leak point</p> <p>3 pressure.</p> <p>4 When it comes to midurethral slings, I</p> <p>5 want to know who has urethral closure pressures that</p> <p>6 are 43 centimeters or lower or 44 centimeters of water</p> <p>7 pressure or higher. I want to know the age of the</p> <p>8 individual and I want to know what her voiding</p> <p>9 function is and whether she has preexisting retention</p> <p>10 and whether she is a Valsalva voider and how strong</p> <p>11 her detrusor contraction is during voiding.</p> <p>12 And then I consider all of those factors</p> <p>13 to then think about whether I want to do a retropubic</p> <p>14 midurethral sling, a transobturator midurethral sling,</p> <p>15 and single incision midurethral sling, a bladder neck</p> <p>16 sling, and depending on the health of the individual,</p> <p>17 whether I'm thinking about doing a full retropubic</p> <p>18 bladder neck sling or whether I would think about</p> <p>19 doing a Capio CL transvaginal sling with no abdominal</p> <p>20 incision as a less invasive procedure.</p> <p>21 So there is a lot that I consider about</p> <p>22 the mode and method that I'm going to use to perform</p> <p>23 the operation. And then secondarily, relatively</p> <p>24 speaking, and this is a fudge, how tight or not I'm</p>	<p style="text-align: right;">Page 61</p> <p>1 tighter, fudge a little bit tighter in that individual</p> <p>2 than I would in the average patient.</p> <p>3 Q. So is it your testimony that the tension</p> <p>4 or lack thereof that you use with respect to a</p> <p>5 transvaginal mesh sling is patient dependent?</p> <p>6 A. Very much so in certain cases, but thank</p> <p>7 goodness in the majority of cases I would do what one</p> <p>8 would consider a standard retropubic or transobturator</p> <p>9 or single incision sling.</p> <p>10 Q. And is it your testimony that with respect</p> <p>11 to certain patients you do insert the sling with</p> <p>12 tension?</p> <p>13 MR. SNELL: I'm going to object, form.</p> <p>14 Go ahead.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Yeah, I think what I was trying to</p> <p>17 communicate is that in some individuals I would place</p> <p>18 a midurethral sling retropubic transobturator or</p> <p>19 single incision with greater or less tension in one</p> <p>20 individual than another.</p> <p>21 BY MS. WATSON:</p> <p>22 Q. Okay. During the time period of 1999 to</p> <p>23 when you stopped using the TVT Retropubic, do you</p> <p>24 believe that you used one product more than the others</p>

<p style="text-align: right;">Page 62</p> <p>1 or not necessarily?</p> <p>2 A. I believe I used one product more than the</p> <p>3 others, yes.</p> <p>4 Q. And which product would that be?</p> <p>5 A. That was the Advantage Fit product.</p> <p>6 Q. Okay. And I believe in your expert report</p> <p>7 you state that you inserted approximately 500 or</p> <p>8 something over 500 surgeries using the TVT Retropubic,</p> <p>9 is that accurate?</p> <p>10 A. Yes.</p> <p>11 Q. And what -- how many Advantage Fits do you</p> <p>12 estimate you've inserted, or implanted, rather?</p> <p>13 A. Probably around 1500, I would guess.</p> <p>14 Q. Okay. And why do you prefer the Advantage</p> <p>15 Fit over the TVT Retropubic?</p> <p>16 MR. SNELL: I'm going to object. That misstates</p> <p>17 the testimony. He did not say he prefers it.</p> <p>18 BY THE WITNESS:</p> <p>19 A. That is correct, it's not a statement if I</p> <p>20 prefer it currently.</p> <p>21 BY MS. WATSON:</p> <p>22 Q. Well, why is it that you've implanted 1500</p> <p>23 Advantage Fits versus 500 TVT Retropubic?</p> <p>24 A. Well, in part it's because in recent years</p>	<p style="text-align: right;">Page 64</p> <p>1 the TVT mesh.</p> <p>2 BY MS. WATSON:</p> <p>3 Q. And you currently hold a teaching</p> <p>4 capacity, right, Doctor?</p> <p>5 A. As I always have, yes.</p> <p>6 Q. In your current teaching capacity, do you</p> <p>7 teach your students how to implant a TVT Retropubic?</p> <p>8 A. Currently, as I stated, I don't have</p> <p>9 access to TVT or TVT Exact to instruct people in -- to</p> <p>10 instruct my residents and fellows except when Ethicon</p> <p>11 participates in or has participated in one of our</p> <p>12 postgraduate courses with a cadaver lab. And on those</p> <p>13 occasions I have been able to teach our fellows how to</p> <p>14 use that product as well as residents who have</p> <p>15 attended those courses or other practicing urologists</p> <p>16 and gynecologists.</p> <p>17 Q. Okay. When was the last time that that</p> <p>18 occurred?</p> <p>19 A. When is the last time that that occurred?</p> <p>20 Let's see. We had a cadaver lab in June for our</p> <p>21 fellows that was -- yeah, actually, no. I don't think</p> <p>22 there were any TVT products at that particular lab.</p> <p>23 The last time that would have occurred probably dates</p> <p>24 back to, I would think 2015, June 2015.</p>
<p style="text-align: right;">Page 63</p> <p>1 I didn't have TVT to choose from, in any event, and</p> <p>2 more importantly TVT Exact. I transitioned originally</p> <p>3 to the Advantage Fit product because I thought, I</p> <p>4 don't think that I'm still of that opinion, but I</p> <p>5 thought there might be some advantages to the</p> <p>6 modifications that Boston Scientific had made to that</p> <p>7 product compared to the original TVT.</p> <p>8 Q. And what did you believe those advantages</p> <p>9 were?</p> <p>10 A. A smaller trochar and I was hopeful that</p> <p>11 the de-tanged mesh in the midportion of the sling</p> <p>12 might cause fewer mesh exposures than the original TVT</p> <p>13 product.</p> <p>14 Q. And do you still believe that those are</p> <p>15 advantages associated with the Advantage Fit?</p> <p>16 MR. SNELL: I'm going to object. And I believe</p> <p>17 that misstates.</p> <p>18 BY THE WITNESS:</p> <p>19 A. I -- I still believe that for me and the</p> <p>20 fellows and residents that I'm teaching that using the</p> <p>21 smaller 3 millimeter trochar is an advantage to the</p> <p>22 original TVT, but obviously not to TVT Exact, but I do</p> <p>23 not believe that there is any evidence, mine or in the</p> <p>24 literature, to support an advantage to alteration of</p>	<p style="text-align: right;">Page 65</p> <p>1 Q. What transvaginal mesh polypropylene</p> <p>2 products do you currently use in your practice to</p> <p>3 treat stress urinary incontinence?</p> <p>4 A. So currently Advantage Fit procedures,</p> <p>5 Aris transobturator midurethral slings, and Coloplast</p> <p>6 single incision midurethral sling, which is called --</p> <p>7 come on, Peter -- Altis single incision midurethral</p> <p>8 slings. Those are pretty much with rare exception if</p> <p>9 I'm trialing a product are the midurethral slings that</p> <p>10 I currently have been using in our ORs.</p> <p>11 Q. Do you also treat stress urinary</p> <p>12 incontinence in women using non-polypropylene</p> <p>13 transvaginal mesh surgeries?</p> <p>14 A. Yes, of course.</p> <p>15 Q. Okay. What surgeries do you do that fall</p> <p>16 into that category?</p> <p>17 A. Well, I think, as I alluded to earlier, we</p> <p>18 do retropubic bladder neck slings using autologous and</p> <p>19 autogenous fascia, anchored to rectus fascia or to</p> <p>20 Cooper's ligament, and then --</p> <p>21 Q. And do you --</p> <p>22 A. Sorry.</p> <p>23 Q. Oh, I'm sorry.</p> <p>24 A. And now I'm forgetting the question.</p>

<p style="text-align: right;">Page 66</p> <p>1 And we also do the occasional Burch 2 urethropexy still to this day as a historic example. 3 Q. Do you find that all of those surgical 4 options that you just mentioned that do not involve 5 polypropylene transvaginal mesh products to be safe 6 and effective? 7 MR. SNELL: Object; form. 8 Go ahead. 9 BY THE WITNESS: 10 A. I find all of those operations to be 11 relatively safe and effective, yes. 12 BY MS. WATSON: 13 Q. Okay. You've mentioned that you've used 14 the TVT Retropubic and the TVT Exact. 15 Have you used any of the other TVT 16 products? 17 A. Which specifically are you referring to? 18 Q. The TVT-Obturator? 19 A. Yes, I have used TVT-O in cadaver labs, 20 but never in a living individual. 21 Q. Okay. And why have you not used it in a 22 living individual? 23 A. I -- I prefer it outside to in and I -- 24 and in the beginning I thought that it was sort of a</p>	<p style="text-align: right;">Page 68</p> <p>1 point where I could do it in the office where I could 2 be more cost effective for -- for economic reasons, 3 but I was very concerned about decreasing the efficacy 4 of these midurethral slings. And, again, the 5 literature bore that out early on with TVT-Secur, but 6 subsequently, you know, we have excellent outcomes and 7 now midterm -- or midterm, that's the wrong term -- 8 you know, two-year data and now even some three-year 9 data that would suggest the same quality outcomes that 10 we expect with full-length retropubic and 11 transobturator midurethral slings when using single 12 incision slings. 13 Q. Does your report cover any products -- 14 strike that. 15 Does your report cover any Ethicon TVT 16 products other than the TVT Retropubic? 17 A. It was not intended to do that, but there 18 are certainly parts of my general report that would be 19 relevant to other products because they are discussing 20 the use of polypropylene mesh for urinary incontinence 21 treatment in general, but not specifically, no. 22 Q. Okay. I believe you testified earlier 23 that you would have started drafting your report in 24 late March or April of 2018, and feel free to correct</p>
<p style="text-align: right;">Page 67</p> <p>1 silly operation that was developed to get around the 2 paying Medroporgis (phonetic) for the rights to 3 perform a transobturator midurethral sling. But 4 subsequently certainly the literature has shown me 5 that I was wrong and that there certainly seemed to be 6 advantages to inside out transobturator midurethral 7 slings that I would not have anticipated previously. 8 But, no, I've never performed the operation in a 9 patient. 10 Q. Have you used the TVT Abbrevio? 11 A. I have not used TVT Abbrevio, no. 12 Q. Okay. Is there a reason for that? 13 A. Not really. I just haven't been exposed 14 to it. 15 Q. Okay. Have you used the TVT-Secur? 16 A. No, I have not used TVT-Secur. 17 Q. And is there a reason for that? 18 A. I was hesitant to start using single 19 incision midurethral slings until very recently. I 20 was concerned because I was having such good outcomes 21 with the full-length traditional retropubic 22 midurethral slings and transobturator slings. I 23 didn't really see any advantage to using a single 24 incision midurethral sling unless we evolved to the</p>	<p style="text-align: right;">Page 69</p> <p>1 me if I'm wrong on that, but when were you first hired 2 to work as an expert in the Ethicon litigation? 3 A. I don't recall exactly when Burt contacted 4 me. I think it was somewhere around early March 5 of 2018. 6 Q. Did you know Burt prior to that? 7 A. I did not. 8 Q. And when Burt reached out to you, what was 9 your understanding as to what he was asking you to do? 10 A. Well, my understanding was that he was 11 interested in me acting as an expert to assist his 12 firm in the litigation of these transvaginal mesh 13 cases in the treatment of urinary incontinence. 14 Q. At that point had you prepared any 15 transvaginal mesh expert reports for, I believe you 16 said AMS? 17 A. Yes, I had. 18 Q. Okay. So at that time you had already 19 prepared a transvaginal mesh expert report, is that 20 correct? 21 A. Yes, that is correct. 22 Q. Okay. And have -- and strike -- I 23 apologize if I've already asked this, and maybe I 24 have, but have you been deposed in any transvaginal</p>

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<p>1 mesh case or litigation prior to today?</p> <p>2 A. Yes, I have, as a treater.</p> <p>3 Q. Okay. And how many times has that</p> <p>4 occurred?</p> <p>5 A. Wow, to the best of my recollection, in</p> <p>6 cases that were -- well, this is hard. I have</p> <p>7 certainly -- well, I'm going to answer twice in cases</p> <p>8 that involved specifically aimed at, quote, mesh</p> <p>9 litigation, end quote, where one I was an implanter</p> <p>10 and one I was a subsequent treater. But I've also</p> <p>11 been deposed in medical malpractice cases, individual</p> <p>12 cases where bladder neck -- well, where mid --</p> <p>13 polypropylene midurethral slings were at issue.</p> <p>14 Q. And with respect to those malpractice</p> <p>15 cases, were you a party in those cases?</p> <p>16 A. Was I the defendant in those cases, is</p> <p>17 that what you mean by saying was I a party in those</p> <p>18 cases?</p> <p>19 Q. Correct.</p> <p>20 A. No, I was not.</p> <p>21 Q. Okay. And do you recall the names of the</p> <p>22 two cases in which you were deposed as a treater in --</p> <p>23 and they were cases in mesh litigation, I think you</p> <p>24 said one you were an implanter and one you were a</p>	<p>1 your -- the one invoice was for \$33,450 and the second</p> <p>2 invoice, I believe, was -- I can't read my own</p> <p>3 handwriting -- I think it was \$17,100, is that</p> <p>4 correct?</p> <p>5 A. I believe so, but I'm going to look back</p> <p>6 at the invoices since I screwed up this question</p> <p>7 earlier.</p> <p>8 Yeah, there is an invoice from June 17th,</p> <p>9 2018, for \$33,450, and a second invoice from</p> <p>10 July 30th, 2018, for \$17,100.</p> <p>11 Q. Does that include preparing for your</p> <p>12 deposition here today?</p> <p>13 A. It does not, as you asked me earlier, that</p> <p>14 work has been subsequent to those earlier invoices.</p> <p>15 Q. Okay. And what did you do to prepare for</p> <p>16 your deposition today?</p> <p>17 A. I went back through, not all, but a large</p> <p>18 number of the articles that I had reviewed, read</p> <p>19 previously, pulled up a couple of things that I hadn't</p> <p>20 looked at for years to -- to review from my files,</p> <p>21 looked at some of the Ethicon documents that Burt's</p> <p>22 firm had sent me, reviewed Dr. Rosenzweig's report, I</p> <p>23 looked at a couple of depositions that had been given</p> <p>24 earlier again in this litigation, I yesterday met with</p>
Page 71	Page 73
<p>1 subsequent treater, do you recall the names of those</p> <p>2 cases?</p> <p>3 A. Boy, it's terrible, no, I don't. I'd have</p> <p>4 to look those -- I'd have to look that up.</p> <p>5 Q. Okay. And were you represented by an</p> <p>6 attorney in those depositions?</p> <p>7 A. I was not.</p> <p>8 Q. I believe you said that you spent ten</p> <p>9 hours drafting your general expert report, is that</p> <p>10 correct?</p> <p>11 A. Yes, that is correct.</p> <p>12 Q. Okay. And does that include a review of</p> <p>13 materials in conjunction with drafting the report?</p> <p>14 A. Well, that -- that's the hard part. So</p> <p>15 some of it, yes and some of it no. You know, I</p> <p>16 probably spent a lot more time reviewing -- well, some</p> <p>17 of the literature you have on this thumb drive -- than</p> <p>18 the ten hours, but specifically then preparing the</p> <p>19 general report and modifying it from a prior general</p> <p>20 report took me about ten hours. So the overall time</p> <p>21 that I spent, I guess, encompassing all of that work</p> <p>22 was far in excess of ten hours.</p> <p>23 Q. Bear with me, Doctor.</p> <p>24 So, I believe you said earlier that</p>	<p>1 defense counsel to review some of these items.</p> <p>2 Q. Okay. Can you estimate how many hours</p> <p>3 you've spent preparing for your deposition today?</p> <p>4 MR. SNELL: Objection; asked and answered.</p> <p>5 BY THE WITNESS:</p> <p>6 A. I believe earlier I stated that I had</p> <p>7 spent, I was guessing, about 18 hours in this past</p> <p>8 week preparing for the deposition today.</p> <p>9 BY MS. WATSON:</p> <p>10 Q. Okay. I apologize for asking that again.</p> <p>11 I forget what I've asked.</p> <p>12 A. No problem.</p> <p>13 Q. And the rate for that -- for those hours</p> <p>14 is \$600 per hour?</p> <p>15 MR. SNELL: Objection; asked and answered.</p> <p>16 Go ahead.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Yes.</p> <p>19 BY MS. WATSON:</p> <p>20 Q. You mentioned that you reviewed some --</p> <p>21 MR. SNELL: I'm sorry, Counsel, I'll withdraw</p> <p>22 that objection. I withdraw that objection. I</p> <p>23 misheard your question.</p> <p>24 BY MS. WATSON:</p>

<p style="text-align: right;">Page 74</p> <p>1 Q. Doctor, you mentioned that you've reviewed 2 some depositions in preparation for your deposition 3 here today.</p> <p>4 Do you recall which depositions you 5 reviewed?</p> <p>6 A. I looked at parts -- well, just recently I 7 looked at parts of Dr. Kim Kenton's deposition and 8 parts of Kathryn Mathews' deposition.</p> <p>9 Q. And was there a reason why you reviewed 10 those two depositions or parts of them?</p> <p>11 A. Well, they were two depositions that 12 Mr. Snell's firm had sent to me and I was curious what 13 sort of questions were asked during the deposition and 14 how my colleagues responded. I was curious about 15 that.</p> <p>16 Q. Okay. Bear with me, Doctor. I think I 17 know the answer to this, but have you done any other 18 general expert reports for Ethicon in the transvaginal 19 mesh litigation aside from the TVT Retropubic report?</p> <p>20 A. No, I have not.</p> <p>21 Q. Do you consider the TVT Retropubic 22 procedure to be a minimally invasive procedure?</p> <p>23 A. Most certainly, yes.</p> <p>24 Q. Bear with me, Doctor, I'm going through my</p>	<p style="text-align: right;">Page 76</p> <p>1 was the teaching attending on a laser case for a 2 condyloma acuminatum and the plaintiff was claiming 3 injuries and scarring from the surgery and negligence, 4 obviously, on our part. The case went to -- the judge 5 put it off to, what do you call it, arbitration, 6 sorry, to arbitration where we won in arbitration 7 showing basically that unfortunately the patient had 8 her laser surgery and never complied with our 9 postoperative instructions regarding use of creams and 10 didn't follow up in the clinic at all for her 11 subsequent care. So anyhow, so that was one.</p> <p>12 The second case was a case where I came in 13 to labor and delivery where a colleague had had a 14 patient who had a uterine rupture and a vaginal birth 15 after cesarean section and she had ruptured her 16 bladder and urethra and part of her vagina. And I 17 came in and reconstructed her urethra, bladder, and 18 part of her vagina, and she was suing me along with 19 the obstetrician and my fellow at the time, Dr. Janet 20 Tomezsko, for negligence in doing her repair and her 21 having subsequent urgency, frequency and urgency 22 urinary incontinence, and I was dropped from that 23 lawsuit before it went to trial.</p> <p>24 And in the third case -- oh, gosh, what's</p>
<p style="text-align: right;">Page 75</p> <p>1 outline. A lot of these questions I've already asked 2 you, so...</p> <p>3 A. Of course.</p> <p>4 Q. Who is your current employer?</p> <p>5 A. My current employer is NorthShore 6 University HealthSystem medical group.</p> <p>7 Q. And how long have you been employed by 8 that employer?</p> <p>9 A. Well, they've changed their name three 10 times since I've been employed by them, but ostensibly 11 I was employed as of March 1st, 1991 by them.</p> <p>12 Q. Okay. Have you ever been named as a 13 defendant in a medical malpractice lawsuit?</p> <p>14 A. I'm sorry. Could you repeat the question?</p> <p>15 Q. Sure.</p> <p>16 Have you ever been named as a defendant in 17 a medical malpractice lawsuit?</p> <p>18 A. Yes, I have.</p> <p>19 Q. Okay. How many times?</p> <p>20 A. I believe three times.</p> <p>21 Q. And can you just briefly and generally 22 explain what the allegations were on those three 23 cases?</p> <p>24 A. Yeah, the first, many, many years ago, I</p>	<p style="text-align: right;">Page 77</p> <p>1 the third case. I'm sorry. I'm not remembering the 2 details of the third case. All of these were many, 3 many years ago. They all, I think, predated 2002.</p> <p>4 Q. Okay. With respect to the third one that 5 you can't recall the circumstances of, do you recall 6 how it was resolved?</p> <p>7 A. Yeah. It was dropped after depositions. 8 It did not go to trial.</p> <p>9 Q. Switching gears a little bit, Doctor, do 10 you hold yourself out as an expert in FDA regulations 11 with respect to medical devices?</p> <p>12 A. Well, as we discussed before, I have a 13 fair amount of expertise in the FDA process regarding 14 devices as well as medications and I've acted as a 15 consultant to numerous companies in developing their 16 products and preparing them for FDA submission and 17 also assisting them, as we talked about earlier, going 18 through the FDA process and testifying before the FDA 19 panel. So, yeah, I think I have a fair amount of 20 expertise in that area.</p> <p>21 Q. Okay. So is it your testimony that you 22 are a regulatory expert with respect to FDA?</p> <p>23 A. Well, I think what I was just discussing 24 and discussed previously would support that I am</p>

<p style="text-align: right;">Page 78</p> <p>1 expert in that area, yes.</p> <p>2 Q. Okay. Do you hold yourself out as an</p> <p>3 expert in the marketing of medical devices?</p> <p>4 A. Well, there, again, also I think I have a</p> <p>5 fair amount of expertise having acted with numerous</p> <p>6 companies over the last 30 years in helping to prepare</p> <p>7 their products for marketing and their Instructions</p> <p>8 for Use to fellow physicians.</p> <p>9 I also have extensive experience as a</p> <p>10 teacher for the last 33 years and two years before</p> <p>11 that in fellowship training residents, now training</p> <p>12 residents, fellows, medical students and fellow</p> <p>13 physicians on an annual basis through lectures, labs,</p> <p>14 courses, as well as actively in the operating room on</p> <p>15 how to use these products.</p> <p>16 So, yes, I think I have a fair amount of</p> <p>17 expertise and have used that expertise as a consultant</p> <p>18 to the companies we had talked about before and others</p> <p>19 to market their products to physicians and</p> <p>20 institutions.</p> <p>21 Q. Have you personally drafted Instructions</p> <p>22 for Use for medical devices?</p> <p>23 A. I personally have been involved in the</p> <p>24 development of Instructions for Use for a couple of</p>	<p style="text-align: right;">Page 80</p> <p>1 A. Well, again, I have a fair amount of</p> <p>2 expertise in biomaterial use clinically and the</p> <p>3 applications in not only using them as well as helping</p> <p>4 to study them in animal models and the bench studies</p> <p>5 that we have done in the past as well as our broad</p> <p>6 clinical experience. I've published extensively in</p> <p>7 the past looking and comparing different products and</p> <p>8 how they are applied for use, their outcomes and</p> <p>9 success when used, biologic products as well as</p> <p>10 synthetic products, in the treatment of urinary</p> <p>11 incontinence as well as genital prolapse. So, yes, I</p> <p>12 think I have quite a bit of expertise in that arena.</p> <p>13 Q. Okay. So it's your testimony that you are</p> <p>14 an expert in biomaterials?</p> <p>15 MR. SNELL: Objection; asked and answered. He</p> <p>16 just said yes.</p> <p>17 BY MS. WATSON:</p> <p>18 Q. Doctor, do you -- is it your testimony</p> <p>19 that you hold yourself out as an expert in</p> <p>20 biomaterials?</p> <p>21 A. As I stated earlier, yes, I think I have a</p> <p>22 great deal of expertise in that area based on my</p> <p>23 clinical experience as well as my basic science</p> <p>24 research experience.</p>
<p style="text-align: right;">Page 79</p> <p>1 products, yes.</p> <p>2 Q. Okay. And you've -- this may have been</p> <p>3 asked and answered, but can you tell me which products</p> <p>4 that would involve?</p> <p>5 A. Well, recently working with Valencia</p> <p>6 Technologies on developing their Instructions for Use</p> <p>7 for investigators, which will in the future be the</p> <p>8 basis for Instructions for Use for physicians and</p> <p>9 other healthcare providers using the eCoin device, and</p> <p>10 also working currently with Amphora, as we've</p> <p>11 discussed, on patent issues as well as their</p> <p>12 Instructions for Use to investigators, which, again,</p> <p>13 will formulate the basis for their Instructions for</p> <p>14 Use of the commercial product when FDA-approved.</p> <p>15 I've also worked in the past with Novasys</p> <p>16 in their Instructions for Use for products, with EMPI</p> <p>17 and Hollister on their Instructions for Use for</p> <p>18 products and introducing their products into the</p> <p>19 marketplace, and I've also, I think, reviewed</p> <p>20 Instructions for Use for a number of other companies</p> <p>21 that aren't clearly as set in my mind as I sit here</p> <p>22 today.</p> <p>23 Q. Do you hold yourself out as an expert in</p> <p>24 biomaterials?</p>	<p style="text-align: right;">Page 81</p> <p>1 Q. I believe you mentioned that you met with</p> <p>2 Burt yesterday, is that correct?</p> <p>3 A. Yes, that is correct.</p> <p>4 Q. Okay. How long did you guys meet?</p> <p>5 A. Oh, I believe we met roughly for about</p> <p>6 five hours yesterday.</p> <p>7 Q. And prior to meeting yesterday, had you</p> <p>8 met with Burt in person?</p> <p>9 A. Yes, I had.</p> <p>10 Q. Okay. When was that?</p> <p>11 A. I met with Burt in person on two other</p> <p>12 occasions.</p> <p>13 Q. Okay.</p> <p>14 A. One -- gee, I do not remember the exact</p> <p>15 date, but I believe that we met in June or, well,</p> <p>16 maybe it was early July. Yeah, I don't remember</p> <p>17 exactly, June or July. And then, as we had talked</p> <p>18 about earlier, I met with Burt, I believe, back in --</p> <p>19 well, was it March -- earlier in the spring. I'm not</p> <p>20 sure exactly when.</p> <p>21 Q. Okay. And -- and the spring meeting,</p> <p>22 where did that occur?</p> <p>23 A. In my offices in Skokie, Illinois.</p> <p>24 Q. How long did you meet at that time?</p>

<p style="text-align: right;">Page 82</p> <p>1 A. As I sit here today, I certainly can't 2 remember exactly. I don't think it was too long, 3 that -- that initial meeting. Maybe an hour, 4 45 minutes, but I -- I don't recall exactly. 5 Q. Did you submit an invoice for that 6 meeting? 7 A. No, I did not submit an invoice for that 8 meeting. 9 Q. And then with respect to the meeting in 10 June or July, how long did that meeting last? 11 A. Wow, how long did that meeting last. I 12 think we met for about -- well, to discuss work, we 13 met for about, I would guess around three hours, maybe 14 three-and-a-half. 15 Q. Did you submit an invoice for that 16 meeting? 17 A. I did. 18 Q. And where did that meeting occur? 19 A. That meeting started in my offices in 20 Skokie and then ended in my home in Winnetka, 21 Illinois. 22 Q. And have you met with any other lawyers 23 for Ethicon aside from Burt? 24 A. I have not.</p>	<p style="text-align: right;">Page 84</p> <p>1 A. Well, in looking at some of the documents 2 that I reviewed, laser cutting the mesh blunts the 3 lateral edges of the mesh and avoids any tiny, tiny 4 little pieces of mesh that might fall off the mesh 5 subsequently. And it minimally changes the 6 distensibility of the mesh when placed under a load. 7 Certainly at physiologic levels that difference is 8 minimal, almost nothing. 9 Q. What documents did you review that 10 informed you of those differences? 11 A. Those were some studies done by Ethicon, 12 their scientists. 13 Q. And prior to reviewing those studies, did 14 you ever -- well, strike that. 15 Prior to reviewing those studies, were you 16 aware of a difference in the characteristics between 17 the laser cut mesh and mechanically cut mesh? 18 MR. SNELL: Object to form. 19 Go ahead. 20 BY THE WITNESS: 21 A. To some degree, yes, because when I was 22 still working as an adviser for Boston Scientific and 23 they were developing the Advantage Fit product, it was 24 clear to me during the development and my consulting</p>
<p style="text-align: right;">Page 83</p> <p>1 Q. Have you had any -- some conferences with 2 Burt or any other Ethicon lawyers? 3 A. I have had some phone conversations over 4 the last six months with Burt but no other attorneys 5 regarding this litigation. 6 Q. Can you estimate how many phone 7 conversations you've had with Burt? 8 A. Oh, how many phone conversations have I 9 had with Burt? I would guess somewhere in the range 10 of four or five. 11 Q. And can you estimate how long those phone 12 conversations have been? 13 A. Oh, they've all been very brief. 14 (WHEREUPON, there was a short 15 interruption.) 16 BY MS. WATSON: 17 Q. All right. Bear with me for a second. 18 I'm crossing questions off of my outline here. 19 Doctor, do you find that there is a 20 difference in the characteristics of the laser cut 21 mesh versus a mechanically cut mesh? 22 A. Are there differences in the 23 characteristics. Well, yes. 24 Q. And what are those differences?</p>	<p style="text-align: right;">Page 85</p> <p>1 with them that by applying heat of any source to the 2 edge of the polypropylene mesh that you would, quote, 3 de-tange it or, you know, blunt the edges of the mesh. 4 BY MS. WATSON: 5 Q. Okay. In your clinical practice in using 6 the TVT product, did you ever notice a difference 7 between the laser cut mesh and the mechanically cut 8 mesh? 9 A. I'm not sure that I ever used the TVT 10 Exact product with the laser cut mesh. 11 Q. Okay. 12 A. I mean, let me qualify that. As I 13 discussed earlier about timelines, I don't believe 14 that I ever used the laser cut mesh in TVT Exact in a 15 patient. I had experience with it in the cadaver lab. 16 Q. Okay. So my question was probably a poor 17 one. 18 In your clinical practice, if you were to 19 be provided with a TVT product, would you be able to 20 tell whether it was laser cut or mechanically cut just 21 based on the product itself? 22 A. I would move to feel the edge of the mesh 23 outside of the sheath to be able to ascertain that. 24 And, yes, I believe I probably could tell the</p>

<p style="text-align: right;">Page 86</p> <p>1 difference.</p> <p>2 Q. When was the last time you implanted a</p> <p>3 polypropylene mesh sling in a woman to treat stress</p> <p>4 urinary incontinence?</p> <p>5 A. Monday.</p> <p>6 Q. Okay. So, and was that the Advantage Fit?</p> <p>7 A. I did an Altis single incision midurethral</p> <p>8 sling on Monday the 24th and I did a retropubic</p> <p>9 midurethral sling, which was an Advantage Fit, yes.</p> <p>10 Q. You talked earlier about some of the</p> <p>11 surgical treatment options to treat stress urinary</p> <p>12 incontinence that do not involve polypropylene mesh</p> <p>13 slings, and my question is: Do you teach those</p> <p>14 procedures in your teaching practice?</p> <p>15 A. Yeah. Well, to be clear, my clinical</p> <p>16 practice and my teaching practice are one in the same.</p> <p>17 Q. Okay.</p> <p>18 A. So I'm accompanied in the OR every Monday</p> <p>19 and sometimes other days of the week by at least one</p> <p>20 of our clinical fellows in female pelvic medicine and</p> <p>21 reconstructive surgery and one or more residents and</p> <p>22 sometimes medical students in the operating room. So</p> <p>23 when I'm operating, they are operating, and we are</p> <p>24 teaching.</p>	<p style="text-align: right;">Page 88</p> <p>1 Beach, California to do my fellowship there, we had</p> <p>2 made a rental agreement with a physician there to rent</p> <p>3 his -- one of his condominiums, and when we got there,</p> <p>4 he told us that we hadn't confirmed anything, et</p> <p>5 cetera, et cetera; namely, we couldn't move into the</p> <p>6 condo. He had rented it out to someone else. And,</p> <p>7 you know, we said, You can't do that, you know, it's</p> <p>8 terrible, we want our money back, et cetera, fought</p> <p>9 with him and had to live elsewhere for a month until</p> <p>10 we could obtain another similar condo in the same</p> <p>11 complex. And so before we could think to sue him, he</p> <p>12 sued us or threatened to sue us. And sent us legal</p> <p>13 notice and it never went beyond that.</p> <p>14 Q. Okay. Bear with me, Doctor.</p> <p>15 Okay. Doctor, I have, let's see, a few</p> <p>16 questions.</p> <p>17 A. As many as you want.</p> <p>18 Q. I appreciate that.</p> <p>19 MR. SNELL: Yeah, I'm going to object to that</p> <p>20 statement.</p> <p>21 THE WITNESS: I am overenthusiastic. I'm sorry.</p> <p>22 As many as you want within the allotted time.</p> <p>23 BY MS. WATSON:</p> <p>24 Q. Doctor, I'd ask you to look at Exhibit 5,</p>
<p style="text-align: right;">Page 87</p> <p>1 Q. Okay. That makes sense.</p> <p>2 Aside from the medical malpractice actions</p> <p>3 that we've discussed, have you ever been a party to a</p> <p>4 lawsuit?</p> <p>5 A. I'm not fully understanding your question,</p> <p>6 so let me just question --</p> <p>7 Q. Sure, so I'll rephrase it if you want me</p> <p>8 to.</p> <p>9 A. Sure, thanks.</p> <p>10 Q. Aside from being a defendant in a medical</p> <p>11 malpractice action, have you been a plaintiff or a</p> <p>12 defendant in any other sort of lawsuit?</p> <p>13 A. Ah, okay.</p> <p>14 So civil lawsuits you are discussing,</p> <p>15 right?</p> <p>16 Q. Yes.</p> <p>17 A. Yeah. No, I don't think I have been,</p> <p>18 nothing that's gone to court. Somebody once</p> <p>19 threatened me that they were going to sue me and I</p> <p>20 think they sent me legal notice, but it didn't go</p> <p>21 beyond that.</p> <p>22 Q. Okay. And why were they threatening to</p> <p>23 sue you?</p> <p>24 A. Well, years ago when I moved out to Long</p>	<p style="text-align: right;">Page 89</p> <p>1 which is an e-mail exchange from June of 2009, and let</p> <p>2 me know when you've got that in front of you, please.</p> <p>3 A. Okay. I shall.</p> <p>4 Q. Okay. Doctor, do you have Exhibit 5 in</p> <p>5 front of you?</p> <p>6 A. I do.</p> <p>7 Q. Okay. And I'm going to read the e-mail at</p> <p>8 the start of this chain which is dated June 19th,</p> <p>9 2009, from Piet Hinoul.</p> <p>10 Do you know Ms. Piet Hinoul?</p> <p>11 A. I do not personally.</p> <p>12 Q. Okay. And the subject is "Prosima." And</p> <p>13 I'm going to read it and ask you if I read it</p> <p>14 correctly and then ask you some follow-up questions.</p> <p>15 "Dear Friends, Marc Slack just presented</p> <p>16 the Prosima one-year data. The paper was very well</p> <p>17 received. The interest especially in the VSD is huge.</p> <p>18 The moderator, Peter Sand, suggested performing an RCT</p> <p>19 with traditional repairs using the VSD as a control</p> <p>20 group. I absolutely agree. Of note, yesterday a poll</p> <p>21 of more showed that about three-fourths of the 300</p> <p>22 urogynaes claimed that they do not think that the</p> <p>23 future of pelvic floor repairs will be mesh based!</p> <p>24 The world is ready for the VSD revolution! Kind</p>

<p style="text-align: right;">Page 90</p> <p>1 regards, Piet."</p> <p>2 Did I read that correctly?</p> <p>3 A. Yes, that's what I have here.</p> <p>4 Q. Okay. Do you recall being a moderator of</p> <p>5 some sort of program in June of 2009?</p> <p>6 A. I do not.</p> <p>7 Q. Okay.</p> <p>8 A. Sorry. I'm frequently a moderator at our</p> <p>9 scientific meetings.</p> <p>10 Q. Okay. And what does VSD stand for?</p> <p>11 A. As I sit here today, I do not know. Can</p> <p>12 you tell me?</p> <p>13 Q. Based on my research, it is vaginal</p> <p>14 support device.</p> <p>15 Does that sound correct?</p> <p>16 A. Oh, okay. All right. There you go. Yes,</p> <p>17 I know what you are talking about, yeah.</p> <p>18 Q. And do you recall suggesting performing a</p> <p>19 randomized control trial with traditional pairs using</p> <p>20 a vaginal support device?</p> <p>21 A. Well, I don't recall that exact instance,</p> <p>22 but that's helpful. I was talking to you before about</p> <p>23 developing a product that I submitted to Coloplast and</p> <p>24 it was in parallel and very similar to this device.</p>	<p style="text-align: right;">Page 92</p> <p>1 BY THE WITNESS:</p> <p>2 A. Yeah, that's a mischaracterization. I</p> <p>3 have not stopped using polypropylene mesh for prolapse</p> <p>4 surgery when patients request that after giving</p> <p>5 informed consent about all alternative procedures. So</p> <p>6 I still do --</p> <p>7 BY MS. WATSON:</p> <p>8 Q. There --</p> <p>9 A. -- use --</p> <p>10 Q. Sorry, Doctor.</p> <p>11 A. So I still do use polypropylene mesh in</p> <p>12 some selected cases.</p> <p>13 Q. Okay. And that was a poor question. I</p> <p>14 appreciate your answer.</p> <p>15 Do you implant it vaginally?</p> <p>16 A. Yes, I use a transvaginal mesh kit. I'll</p> <p>17 step forward to help clarify, the Uphold LITE kit now</p> <p>18 and have done extensive research on that product as it</p> <p>19 was developed within our own division by my trainee,</p> <p>20 colleague, Dr. Roger Goldberg.</p> <p>21 Q. Okay. Doctor, moving on to Exhibit No. 6,</p> <p>22 please, which is a -- an e-mail chain from June</p> <p>23 of 2006.</p> <p>24 MR. SNELL: Exhibit 6.</p>
<p style="text-align: right;">Page 91</p> <p>1 And I thought the idea of a vaginal support device</p> <p>2 might be very, very helpful in ensuring short-term</p> <p>3 healing and leading to better long-term outcomes, not</p> <p>4 just with the use of biologic grafts, but also just</p> <p>5 with native tissue surgery, and I'm sure it -- not</p> <p>6 recalling the exact moment, but, yes, I mean, I felt</p> <p>7 strongly that I -- well, I felt strongly.</p> <p>8 My hypothesis at the time was that a lot</p> <p>9 of the benefit that Marc was presenting at the time</p> <p>10 might have just come from the support device and not</p> <p>11 necessarily the graft.</p> <p>12 Q. Okay. And do you recall in -- well,</p> <p>13 strike that.</p> <p>14 Doctor, have you ever used polypropylene</p> <p>15 transvaginal mesh to treat pelvic organ prolapse?</p> <p>16 A. Oh, I most certainly have and have</p> <p>17 published on that, too.</p> <p>18 Q. Okay. And when did you stop using</p> <p>19 polypropylene transvaginal mesh to treat pelvic organ</p> <p>20 prolapse?</p> <p>21 MR. SNELL: I'm going to object to --</p> <p>22 BY THE WITNESS:</p> <p>23 A. That's a mischaracterization.</p> <p>24 MR. SNELL: Yeah. No, go ahead.</p>	<p style="text-align: right;">Page 93</p> <p>1 Okay. Thank you, Counsel. We all have it</p> <p>2 and we are ready.</p> <p>3 BY MS. WATSON:</p> <p>4 Q. All right. And Doctor, just to kind of --</p> <p>5 feel free -- I'll just give you a minute to read that</p> <p>6 first paragraph, if you don't mind.</p> <p>7 A. Yeah.</p> <p>8 Q. Let me know when you have had a chance.</p> <p>9 A. Yes, I am familiar with this, something</p> <p>10 that occurred regularly, yeah.</p> <p>11 MR. SNELL: Just take a minute and read it so</p> <p>12 that she can...</p> <p>13 THE WITNESS: Okay. Sorry.</p> <p>14 BY MS. WATSON:</p> <p>15 Q. Doctor, have you had a chance to review</p> <p>16 it?</p> <p>17 A. I have.</p> <p>18 Q. Okay. I'm sorry. I didn't know if you</p> <p>19 were waiting on me or vice versa.</p> <p>20 Do you recall hosting a conference titled</p> <p>21 "Advances in Urogynecology and Pelvic Reconstructive</p> <p>22 Surgery"?</p> <p>23 A. Yes, until last year I hosted this course</p> <p>24 annually for, I think, about 28 years. So yes.</p>

<p style="text-align: right;">Page 94</p> <p>1 Q. Okay. And was there a sponsor for the</p> <p>2 course?</p> <p>3 A. Well, yes. Myself, Northwestern</p> <p>4 University Medical School in the early years, and then</p> <p>5 after our divorce, the University of Chicago Pritzker</p> <p>6 School of Medicine in subsequent years, and we would</p> <p>7 solicit support from various companies in the form of</p> <p>8 unrestricted educational grants and also charge people</p> <p>9 an exhibit fee if different companies wanted to come</p> <p>10 exhibit during the didactic portion of the meeting as</p> <p>11 well as at the cadaver lab and hands-on -- well, it</p> <p>12 wasn't just cadaver, hands-on lab with a cadaver lab.</p> <p>13 Q. Okay. And during the didactic portion,</p> <p>14 would transvaginal mesh products typically be</p> <p>15 discussed?</p> <p>16 A. Yes. It was always, since their</p> <p>17 introduction it was always a source of interest with</p> <p>18 numerous publications coming out and new information</p> <p>19 to share with people, the good and the bad.</p> <p>20 Q. Okay. And then with respect to this</p> <p>21 cadaver lab, what was specifically taught during that</p> <p>22 portion of the event?</p> <p>23 A. Yeah, well, I mean, it evolved over the</p> <p>24 course of years. Early on when I first started doing</p>	<p style="text-align: right;">Page 96</p> <p>1 Q. Okay. With respect -- well, strike that.</p> <p>2 During the cadaver portion of the event,</p> <p>3 did you typically cover the implantation of</p> <p>4 transvaginal mesh products?</p> <p>5 A. In the years that there were transvaginal</p> <p>6 mesh products and the companies that produced them</p> <p>7 were present and/or donated materials to us and in</p> <p>8 kind grants to use to show participants how to use</p> <p>9 them, we used them.</p> <p>10 Q. Okay. Were -- well, strike that.</p> <p>11 To your knowledge, did Ethicon ever donate</p> <p>12 its transvaginal mesh products so that you could use</p> <p>13 them to educate the participants during the cadaver</p> <p>14 portion of the event?</p> <p>15 A. Yes, that occurred for several years.</p> <p>16 Q. Okay. Doctor, I want to move on to -- I</p> <p>17 missed one question about your CV, and it is -- I know</p> <p>18 you have an updated one, but just because it's the one</p> <p>19 in front of me, I'd rather use 3A.</p> <p>20 A. Okay. I will use 3A.</p> <p>21 Q. Would you please turn to Page 65.</p> <p>22 A. Okay. I've got it. Can you ask whatever</p> <p>23 you were asking a moment ago again?</p> <p>24 Q. Yes.</p>
<p style="text-align: right;">Page 95</p> <p>1 the course before it was -- well, when I was still at</p> <p>2 Rush, the -- we were primarily teaching people pelvic</p> <p>3 and retropubic anatomy and then how to perform various</p> <p>4 operations to treat urinary incontinence and genital</p> <p>5 prolapse, as well as sometimes instructing</p> <p>6 gynecologists who weren't familiar with doing</p> <p>7 cystoscopy how to do cystoscopy, urethral</p> <p>8 catheterization and various different skills. And as</p> <p>9 the products that were available and the interest of</p> <p>10 learners, the gynecologists and urologists and other</p> <p>11 healthcare providers attending the meeting, the lab</p> <p>12 would evolve.</p> <p>13 It -- it also had numerous -- well, in</p> <p>14 more recent years, we had to divide out the CME</p> <p>15 portion of the lab from the non-CME portion of the</p> <p>16 lab; namely, during the lab when we had companies,</p> <p>17 Ethicon and others, present in the lab and we were</p> <p>18 using their medical devices to perform or facilitate</p> <p>19 some of these operations, that became a non-CME and</p> <p>20 optional portion of the lab. But back at this point</p> <p>21 in time at this memo in 2006, that was not an issue</p> <p>22 and so we admixed demonstrating anatomy and then that</p> <p>23 anatomy as it was relevant to these individual</p> <p>24 procedures.</p>	<p style="text-align: right;">Page 97</p> <p>1 Would you please turn to Page 65 of</p> <p>2 Exhibit 3A?</p> <p>3 A. I am there.</p> <p>4 Q. Okay. And it looks like this portion is</p> <p>5 the Invited Lectures/Grand Rounds portion of your CV.</p> <p>6 And No. 65 on Page 65 reads, in quote, "The SPARC</p> <p>7 Procedure for Stress Incontinence: A Safer</p> <p>8 Alternative to TVT."</p> <p>9 Do you see that?</p> <p>10 A. I do.</p> <p>11 Q. Do you recall being part of that lecture</p> <p>12 or grand round?</p> <p>13 A. I do.</p> <p>14 Q. And at that time did you believe that the</p> <p>15 SPARC procedure was the safer alternative than the</p> <p>16 TVT?</p> <p>17 A. I believed that it might, but ironically,</p> <p>18 right after this presentation, the chairman of urology</p> <p>19 put a SPARC right through the woman's bladder neck as</p> <p>20 he was inserting the device. So I don't think they</p> <p>21 concluded that it was a safer procedure than the TVT.</p> <p>22 Q. What did you believe?</p> <p>23 A. I believed that -- at that time I believe</p> <p>24 that theoretically SPARC might offer a safety</p>

<p style="text-align: right;">Page 98</p> <p>1 advantage over TVT in terms of decreasing the risk of</p> <p>2 trauma to major blood vessels and the bowel during the</p> <p>3 performance of a retropubic midurethral sling, but</p> <p>4 subsequently, as you'll see on my CV, we showed that</p> <p>5 SPARC wasn't as effective and there really wasn't a</p> <p>6 safety difference compared to TVT and we stopped doing</p> <p>7 SPARC procedures, sadly.</p> <p>8 Q. Okay. You can set that aside and please</p> <p>9 move on to Exhibit 7, which is -- and I'm just going</p> <p>10 to read, but I know you know exactly what it is:</p> <p>11 "An International Urogynecological</p> <p>12 Association (IUGA)/International Continence Society</p> <p>13 (ICS) joint terminology and classification of the</p> <p>14 complications related directly to the insertion of</p> <p>15 prostheses (meshes, implants, tapes) & grafts in</p> <p>16 female pelvic floor surgery."</p> <p>17 Did I read that correctly, Doctor?</p> <p>18 A. Indeed you did.</p> <p>19 Q. Okay. And were you one of the doctors who</p> <p>20 developed the joint terminology and classification?</p> <p>21 A. Yes, as a member of the IUGA terminology</p> <p>22 committee, I helped prepare this document by editing</p> <p>23 it.</p> <p>24 Q. Okay. And what is your understanding as</p>	<p style="text-align: right;">Page 100</p> <p>1 grafts for the treatment of genital prolapse, we were</p> <p>2 hearing about and we were seeing more abstracts</p> <p>3 presented, not just on the efficacy, objective and</p> <p>4 subjective, but also on the complications.</p> <p>5 And these reports at that time, and</p> <p>6 unfortunately still to this date, were being reported</p> <p>7 by different -- by all sorts of different means. And</p> <p>8 there was no way, for example, for people to quantify,</p> <p>9 qualify those clearly because in different</p> <p>10 publications they looked different and sounded</p> <p>11 different.</p> <p>12 And so there was a desire between the two</p> <p>13 international organizations to improve the quality of</p> <p>14 the medical literature and evidence by trying to</p> <p>15 create standardization. So that was the practical</p> <p>16 reason that we wanted to do the project and the</p> <p>17 political reason.</p> <p>18 Q. Okay. In your clinical practice, I think</p> <p>19 you started using other medical devices during</p> <p>20 surgery, and I'm just talking generally, not -- not</p> <p>21 just limited to stress urinary incontinence, is that</p> <p>22 true?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. Is there a reason why, with respect</p>
<p style="text-align: right;">Page 99</p> <p>1 to why this joint terminology and classification was</p> <p>2 developed?</p> <p>3 A. That's a -- well, there is a political</p> <p>4 answer to that and then there is a practical answer to</p> <p>5 that. I presume you want to hear about the practical</p> <p>6 answer and not the political, is that correct?</p> <p>7 Q. I prefer to hear about both, actually.</p> <p>8 A. You prefer to hear about both, okay.</p> <p>9 The political reason was in part because</p> <p>10 we were working at that time, when I was president of</p> <p>11 IUGA, we were working on trying to improve our</p> <p>12 relationship with ICS, and I had been desirous as an</p> <p>13 ICS member also to be involved on their terminology</p> <p>14 committee, but for political reasons they didn't want</p> <p>15 that to happen. So we worked hard to get together</p> <p>16 with a new terminology committee chair at ICS to work</p> <p>17 on doing a project together to show a united front</p> <p>18 amongst all physicians, urology, urogynecology, and</p> <p>19 all non-physician members of the ICS on collaborating</p> <p>20 on important issues.</p> <p>21 The practical issue was we looked for what</p> <p>22 were interesting and hot topics at the time that</p> <p>23 people would need a report for, want a report for.</p> <p>24 And with the introduction of polypropylene meshes and</p>	<p style="text-align: right;">Page 101</p> <p>1 to those surgical procedures and medical devices, that</p> <p>2 there is no joint terminology and classification of</p> <p>3 the complications related to those products?</p> <p>4 MR. SNELL: Objection.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Well, there are. In a way this document</p> <p>7 was supposed to cover complications of -- of all</p> <p>8 grafts that we were placing, prosthesis as well as all</p> <p>9 foreign materials. So, for example, we could qualify</p> <p>10 it when I have a Gore-Tex suture from a sacrospinous</p> <p>11 vaginal vault suspension or a -- even a Vicryl suture</p> <p>12 spit through the vaginal wall after a reconstructive</p> <p>13 surgery, so absorbable or non-absorbable synthetic</p> <p>14 material. If those spit through, we could qualify and</p> <p>15 quantify and classify that information used in this</p> <p>16 document. The same is true when I use an autologous</p> <p>17 or autogenous fascial graft. If I have an exposure, I</p> <p>18 would quantify, qualify that with the same system</p> <p>19 brought forward in this document.</p> <p>20 So the title, while very, very long,</p> <p>21 probably should have been maybe even qualified more,</p> <p>22 but most of us think about grafts as both biologic and</p> <p>23 synthetic materials.</p> <p>24 Q. I guess my question is a little bit</p>

<p style="text-align: right;">Page 102</p> <p>1 different.</p> <p>2 A. Sorry.</p> <p>3 Q. And I guess -- well, it is not your fault.</p> <p>4 I think I did a bad job in asking it.</p> <p>5 Do you use -- strike that.</p> <p>6 Do you do surgeries, whether to treat</p> <p>7 incontinence or something else, in your practice where</p> <p>8 you do not use any foreign body prostheses?</p> <p>9 A. Yes.</p> <p>10 Q. Okay.</p> <p>11 A. Well, literally, let me correct that,</p> <p>12 literally no, right, because I am using sutures,</p> <p>13 whether they are absorbable or they are</p> <p>14 non-absorbable, so that's a foreign body.</p> <p>15 Q. Okay. So is it your testimony that this</p> <p>16 document is intended to include sutures, including</p> <p>17 absorbable and non-absorbable?</p> <p>18 A. It -- it certainly can, yes.</p> <p>19 Q. Okay.</p> <p>20 A. And I've got to qualify my prior answer a</p> <p>21 second time because I was incorrect.</p> <p>22 So I was thinking of extirpative and</p> <p>23 reconstructive surgeries, but occasionally I do things</p> <p>24 like a hysteroscopy or a hysteroscopy and D&C or a</p>	<p style="text-align: right;">Page 104</p> <p>1 BY MS. WATSON:</p> <p>2 Q. Do you agree that unusual discomfort or</p> <p>3 pain, including dyspareunia, are risks associated with</p> <p>4 the TVT Retropubic?</p> <p>5 A. Again, I think that's something that could</p> <p>6 occur with any of the reconstructive surgeries and</p> <p>7 anti-incontinence operations I perform.</p> <p>8 Q. So is your answer yes to that question?</p> <p>9 A. My answer is yes to that question.</p> <p>10 Q. Do you agree that pain associated with</p> <p>11 physical activity is a risk associated with the TVT</p> <p>12 Retropubic device?</p> <p>13 A. I just have never seen that. I've</p> <p>14 certainly heard of that, but I have not seen that. So</p> <p>15 I'm not so sure that I would agree yes to that.</p> <p>16 Q. Okay. Do you agree that spontaneous pain</p> <p>17 is a risk associated with a TVT Retropubic?</p> <p>18 A. I'm not sure I understand what you mean by</p> <p>19 "spontaneous pain." Is that like Michael Jackson's</p> <p>20 head lighting on fire spontaneously or there was</p> <p>21 causes for that?</p> <p>22 Q. It is in the bottom corner of Page 7.</p> <p>23 A. Okay.</p> <p>24 Q. It says:</p>
<p style="text-align: right;">Page 103</p> <p>1 cystoscopy or a cystoscopy where I am distending the</p> <p>2 bladder or injecting things and in those surgeries I</p> <p>3 don't introduce any foreign bodies.</p> <p>4 Q. Okay. And with respect to the</p> <p>5 complications that are listed within this document,</p> <p>6 would you agree that all of the complications listed</p> <p>7 in here can be associated with the TVT Retropubic?</p> <p>8 MR. SNELL: I'm going to object to form,</p> <p>9 overbroad.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Could you help me a little bit because it</p> <p>12 is a big document, could we be more specific and take</p> <p>13 me to a certain part of the document? Do you want to</p> <p>14 look at the categories, is that what you are referring</p> <p>15 to on Page 7?</p> <p>16 BY MS. WATSON:</p> <p>17 Q. Yes.</p> <p>18 Do you agree that mesh exposure and</p> <p>19 extrusion are risks associated with the TVT</p> <p>20 Retropubic?</p> <p>21 A. Yes, and all foreign materials I put in</p> <p>22 the vagina, yes, or insert transvaginally.</p> <p>23 MS. WATSON: I would object to your answer after</p> <p>24 "yes."</p>	<p style="text-align: right;">Page 105</p> <p>1 "The addition of an 'e,'" meaning, I</p> <p>2 guess, subcategory, "to the category code specifies a</p> <p>3 pain, spontaneously present (i.e. without physical</p> <p>4 activity), is associated with the abnormal finding."</p> <p>5 Does that clarify what spontaneous pain</p> <p>6 means?</p> <p>7 A. Ah, I see what you are saying. I don't</p> <p>8 see where it is, but I heard what you are saying.</p> <p>9 Hold just a minute.</p> <p>10 Yes, now I see it. I'm sorry. Yes.</p> <p>11 So 1Be through 3Be, right.</p> <p>12 Q. I'll just ask the question again.</p> <p>13 A. Right. So, yes, so you are asking me,</p> <p>14 could pain exist following a TVT procedure when</p> <p>15 someone is sitting at rest or lying at rest, right?</p> <p>16 Q. Right.</p> <p>17 A. Okay. Again, I'm not sure I can agree</p> <p>18 with that because I've never witnessed that. I'm</p> <p>19 skeptical about that, but I have heard of it occurring</p> <p>20 in, yes, in some reports.</p> <p>21 Q. Okay. Do you agree that clinical</p> <p>22 infection is a risk associated with the TVT</p> <p>23 Retropubic?</p> <p>24 MR. SNELL: Object to the form.</p>

<p style="text-align: right;">Page 106</p> <p>1 BY THE WITNESS:</p> <p>2 A. Clinical infection is a risk with any</p> <p>3 procedure when we break the integrity of the</p> <p>4 epithelium.</p> <p>5 BY MS. WATSON:</p> <p>6 Q. So is your answer to my question yes?</p> <p>7 A. As it would be for --</p> <p>8 MR. SNELL: Same objection.</p> <p>9 THE WITNESS: Sorry.</p> <p>10 BY THE WITNESS:</p> <p>11 A. As it would be for any incontinence</p> <p>12 operation that I perform.</p> <p>13 BY MS. WATSON:</p> <p>14 Q. Do you agree that -- and just for your</p> <p>15 reference, if you turn to Page 9, that's where I'm</p> <p>16 going, do you agree that infection that can cause pain</p> <p>17 is a risk associated with a TVT Retropubic?</p> <p>18 A. Yes, if there is infection, I would expect</p> <p>19 that pain would be a reasonable occurrence or at least</p> <p>20 tenderness if not spontaneous pain.</p> <p>21 Q. Do you agree that abscess formation is a</p> <p>22 risk associated with the TVT Retropubic?</p> <p>23 A. Again, the insertion of any foreign body</p> <p>24 into the human body can result in an abscess.</p>	<p style="text-align: right;">Page 108</p> <p>1 TVT Retropubic?</p> <p>2 A. Yes, it is a risk associated with the</p> <p>3 retropubic TVT.</p> <p>4 Q. Okay. And just so that you don't think</p> <p>5 I'm crazy, we are almost done with this portion,</p> <p>6 Doctor --</p> <p>7 A. I have never thought that you were crazy</p> <p>8 during the conduct of this deposition and I have no</p> <p>9 information or reason to presume that.</p> <p>10 Q. Well, I appreciate that.</p> <p>11 Do you agree that rectal or bowel</p> <p>12 compromise or perforation is a risk associated with</p> <p>13 the TVT Retropubic?</p> <p>14 MR. SNELL: Object to form.</p> <p>15 BY THE WITNESS:</p> <p>16 A. I believe that that has been reported in</p> <p>17 rare cases with the TVT procedure.</p> <p>18 BY MS. WATSON:</p> <p>19 Q. Do you agree that skin and/or</p> <p>20 musculoskeletal complications are risks associated</p> <p>21 with the TVT Retropubic?</p> <p>22 MR. SNELL: Counsel, I think we -- I think your</p> <p>23 question was cut off, if you are referring to</p> <p>24 Subject 6C?</p>
<p style="text-align: right;">Page 107</p> <p>1 Q. And do you agree that what it says there,</p> <p>2 "this is a more serious possibility with a synthetic</p> <p>3 prosthesis or graft"?</p> <p>4 A. Your question is do I agree with that</p> <p>5 statement being valid?</p> <p>6 Q. Yes.</p> <p>7 A. Yes, when there is a foreign body present</p> <p>8 in an abscess, it's more complicated than when there</p> <p>9 is not, because we would have to drain the abscess and</p> <p>10 also usually in most cases remove the foreign body to</p> <p>11 ensure healing.</p> <p>12 Q. Do you agree that it's a more serious</p> <p>13 possibility with a synthetic prosthesis or graft?</p> <p>14 A. The purpose of this statement is to</p> <p>15 include all foreign bodies, okay. So I don't know if</p> <p>16 you are trying to interpret it as synthetic, whether</p> <p>17 it's a prosthesis or a graft. I'm interpreting it and</p> <p>18 the intention of this document was to say synthetic</p> <p>19 grafts or synthetic prostheses and grafts, as in all</p> <p>20 other, namely biologic materials.</p> <p>21 Q. Okay.</p> <p>22 A. So, yes, I agree with that.</p> <p>23 Q. Okay. And do you agree that urinary tract</p> <p>24 compromise or perforation is a risk associated with a</p>	<p style="text-align: right;">Page 109</p> <p>1 MS. WATSON: 6, Category 6.</p> <p>2 MR. SNELL: Oh, okay. Okay. Okay. I'm sorry.</p> <p>3 BY THE WITNESS:</p> <p>4 A. I see. And I'm sorry. Just ask me the</p> <p>5 question again real quickly. Sorry to delay you.</p> <p>6 BY MS. WATSON:</p> <p>7 Q. Sure.</p> <p>8 Do you agree that skin and/or</p> <p>9 musculoskeletal complications are risks associated</p> <p>10 with the TVT Retropubic?</p> <p>11 MR. SNELL: Object to form.</p> <p>12 Go ahead.</p> <p>13 BY THE WITNESS:</p> <p>14 A. Yes, they could be.</p> <p>15 BY MS. WATSON:</p> <p>16 Q. Okay. Do you agree that bleeding</p> <p>17 complications including hematoma are risks associated</p> <p>18 with the TVT Retropubic?</p> <p>19 A. Yes, I do.</p> <p>20 Q. Do you agree that a risk associated with</p> <p>21 the TVT Retropubic is a major degree of resuscitation</p> <p>22 or intensive care?</p> <p>23 A. That has been reported in very, very rare</p> <p>24 cases, yes.</p>

<p style="text-align: right;">Page 110</p> <p>1 Q. Okay. Do you agree that a risk associated</p> <p>2 with a TVT Retropubic is death?</p> <p>3 A. That has been reported in very, very rare</p> <p>4 cases, yes.</p> <p>5 Q. And do you agree that a risk associated</p> <p>6 with the TVT Retropubic is chronic pelvic pain?</p> <p>7 A. Again, that's a real gray area for me. I</p> <p>8 know that that's been reported. I personally in my</p> <p>9 experience and in reviewing the literature as a whole,</p> <p>10 I'm skeptical whether chronic pelvic pain persists</p> <p>11 after the removal of TVT when there is a marked</p> <p>12 inflammatory response to it in rare individuals.</p> <p>13 Q. Do you agree that there is medical</p> <p>14 literature that does state that there can be chronic</p> <p>15 pain even following removal of mesh?</p> <p>16 MR. SNELL: Objection; foundation.</p> <p>17 Go ahead.</p> <p>18 BY THE WITNESS:</p> <p>19 A. I -- I -- I think when we look at large</p> <p>20 meta-analyses and systemic -- systematic reviews, not</p> <p>21 systemic, excuse me, systematic reviews that we don't</p> <p>22 see reports of such instances. These are case</p> <p>23 reports, very, very low levels of evidence, and in</p> <p>24 that coupled with my clinical experience I really</p>	<p style="text-align: right;">Page 112</p> <p>1 that takes the position that risk associated with</p> <p>2 polypropylene mesh slings such as the TVT Retropubic</p> <p>3 is chronic pelvic pain?</p> <p>4 MR. SNELL: Objection; that's a different</p> <p>5 question and I believe his prior answer was</p> <p>6 responsive.</p> <p>7 Go ahead.</p> <p>8 BY THE WITNESS:</p> <p>9 A. I believe that there are case reports in</p> <p>10 our literature that state that.</p> <p>11 MS. WATSON: If you don't mind, sir, I'm just</p> <p>12 going to take a quick break and I may be done.</p> <p>13 MR. SNELL: That's fine. I think we are close</p> <p>14 to the one hour, probably past. We've been going for</p> <p>15 maybe a little more than an hour, so, yeah, let's do</p> <p>16 it.</p> <p>17 (WHEREUPON, a recess was had</p> <p>18 from 11:47 to 11:57 a.m.)</p> <p>19 MS. WATSON: I don't think I have any more</p> <p>20 questions. So, Burt, your turn.</p> <p>21 MR. SNELL: Okay. Yeah, I don't have a lot</p> <p>22 either.</p> <p>23 EXAMINATION</p> <p>24 BY MR. SNELL:</p>
<p style="text-align: right;">Page 111</p> <p>1 conclude that oftentimes when individuals are</p> <p>2 complaining of chronic pelvic pain beyond this period</p> <p>3 where all of the mesh has been removed that oftentimes</p> <p>4 they seem to have prior medical or psychological</p> <p>5 conditions which might be the etiology of that chronic</p> <p>6 pelvic pain.</p> <p>7 So I am skeptical of independent chronic</p> <p>8 pelvic pain persisting when TVT exposures or</p> <p>9 inflammation surrounding the mesh has been treated</p> <p>10 appropriately medically and the subsequent levator</p> <p>11 myalgia and tenderness that might exist from that</p> <p>12 event or trauma is treated appropriately. I think</p> <p>13 that it is my opinion that in all of the cases that</p> <p>14 I've witnessed personally and in my appreciation of</p> <p>15 the reliable medical literature, Level 1 and Level 2</p> <p>16 evidence, that we just do not see that and I do not</p> <p>17 see that. I think those people are inappropriately</p> <p>18 and undertreated.</p> <p>19 MS. WATSON: Okay. Doctor, I respectfully move</p> <p>20 to strike that answer as nonresponsive.</p> <p>21 BY MS. WATSON:</p> <p>22 Q. My question is: Are you aware of any</p> <p>23 medical literature supporting -- or strike that.</p> <p>24 Are you aware of any medical literature</p>	<p style="text-align: right;">Page 113</p> <p>1 Q. So, Dr. Sand, Burt Snell from Butler Snow.</p> <p>2 I just have some follow-up questions.</p> <p>3 In the first hour of our deposition</p> <p>4 questioning by Plaintiffs' counsel, there were</p> <p>5 questions about biologic grafts.</p> <p>6 Do you recall answering questions about</p> <p>7 biologic grafts?</p> <p>8 A. I do.</p> <p>9 Q. Do biologic grafts, as you were answering</p> <p>10 the question, include -- or let me just back that up.</p> <p>11 When you were answering those questions,</p> <p>12 what did you mean by biologic grafts?</p> <p>13 A. Well, when I think about grafts, I think</p> <p>14 about synthetic or biologic as two subheadings, and</p> <p>15 all of the grafts we use falling under those headings.</p> <p>16 So for me biologic grafts would include</p> <p>17 autologous as well as autogenous materials as well as</p> <p>18 heterografts, grafts from other species, so porcine</p> <p>19 dermis, for example. Any material that's derived from</p> <p>20 a living individual.</p> <p>21 Q. Okay. Thank you for that clarification.</p> <p>22 And with regard to Exhibit No. 7 you were</p> <p>23 just asked about, the IUGA and International</p> <p>24 Incontinence Society joint terminology and</p>

<p style="text-align: right;">Page 114</p> <p>1 classification, was it your testimony that these --</p> <p>2 classification system applies to both synthetic and</p> <p>3 biologic materials?</p> <p>4 A. Yes.</p> <p>5 Q. And does it state that explicitly on the</p> <p>6 first page in the abstract?</p> <p>7 A. Yes, it does.</p> <p>8 Q. And is it correct that it was -- that it</p> <p>9 was the intention of this document to cover not just</p> <p>10 synthetic products but also biologic grafts including</p> <p>11 the autologous slings, cadaveric materials and animal</p> <p>12 materials?</p> <p>13 A. Yes.</p> <p>14 Q. And the risks you were asked about as</p> <p>15 potential risks, are those risks -- you had mentioned</p> <p>16 that those are risks of any incontinence procedure for</p> <p>17 some of them.</p> <p>18 Do you recall giving that testimony?</p> <p>19 A. I do.</p> <p>20 Q. Would those incontinence procedures</p> <p>21 include incontinence procedures utilizing biologic</p> <p>22 materials?</p> <p>23 A. Yes.</p> <p>24 Q. Would it include incontinence procedures</p>	<p style="text-align: right;">Page 116</p> <p>1 hosted is an excellent course and there are 130</p> <p>2 surgeons already signed up from all over the Midwest</p> <p>3 region.</p> <p>4 Did I read that correctly?</p> <p>5 A. Yes, you did.</p> <p>6 Q. Was it typical that this would be a</p> <p>7 well-attended course that you would put on?</p> <p>8 A. Yeah. Over the years the attendance</p> <p>9 ranged from --</p> <p>10 MS. WATSON: I'm sorry, Doctor. I object to the</p> <p>11 form.</p> <p>12 MR. SNELL: Sure.</p> <p>13 BY THE WITNESS:</p> <p>14 A. Over the years, attendance, I believe,</p> <p>15 ranged from 110 to 185 individuals for that course.</p> <p>16 BY MR. SNELL:</p> <p>17 Q. Okay. And during these courses would the</p> <p>18 anatomy pertinent to stress incontinence surgery be</p> <p>19 demonstrated?</p> <p>20 A. Yes.</p> <p>21 Q. Would the anatomy and its relevance to</p> <p>22 devices be demonstrated during these courses?</p> <p>23 A. Well, yeah, as we talked about earlier,</p> <p>24 the -- the incontinence procedures that were available</p>
<p style="text-align: right;">Page 115</p> <p>1 utilizing sutures?</p> <p>2 A. Yes.</p> <p>3 Q. You were asked about whether mesh exposure</p> <p>4 is a potential risk of the TVT.</p> <p>5 Do you recall that?</p> <p>6 A. I do.</p> <p>7 Q. And in your report do you identify what</p> <p>8 you believe is the accurate rate of the TVT mesh</p> <p>9 exposure based on the reliable medical literature?</p> <p>10 A. I do.</p> <p>11 Q. Turn, if you would, to the e-mail that was</p> <p>12 marked from 2006 where you hosted a course titled</p> <p>13 "Advances in Urogynecology and Pelvic Reconstruction</p> <p>14 Surgery Conference"?</p> <p>15 A. Yes, Exhibit 6.</p> <p>16 Q. Thank you.</p> <p>17 Is this the type of course you would host</p> <p>18 over the years of your professional experience?</p> <p>19 A. Yeah. I started to host this course when</p> <p>20 I was working at Rush Medical College back in, I</p> <p>21 believe, 1987 was the first year we put on the course,</p> <p>22 and this course ran annually in June until 2017 was</p> <p>23 the last year of the course.</p> <p>24 Q. This says that -- that the course you</p>	<p style="text-align: right;">Page 117</p> <p>1 to surgeons at the time and the prolapse procedures</p> <p>2 that were available to surgeons at the time we would</p> <p>3 try to review, not just during the lab, in the</p> <p>4 hands-on cadaver lab, but also during the didactic</p> <p>5 portion of the course.</p> <p>6 Q. And if you turn to the next page, it talks</p> <p>7 about brochures, clinical, CD-ROMs, products,</p> <p>8 including TVT being available at this conference.</p> <p>9 Do you see that?</p> <p>10 A. I do, yes.</p> <p>11 Q. And is that consistent with your</p> <p>12 recollection that there would be company materials,</p> <p>13 surgical videos, professional education, CD-ROMS, as</p> <p>14 well as products, such as TVT, at these educational</p> <p>15 events?</p> <p>16 A. Yeah, we would encourage all of the</p> <p>17 supporters, exhibitors attending the meeting each year</p> <p>18 to bring certainly any materials that they could to</p> <p>19 educate the participants in what they were offering.</p> <p>20 And specifically within the cadaver lab, those who</p> <p>21 were participating, we wanted them not to just bring</p> <p>22 product that would be used in the cadaver but</p> <p>23 alongside the cadavers if there was any video or other</p> <p>24 supporting information that would help teach</p>

<p style="text-align: right;">Page 118</p> <p>1 participants about the procedures to bring those 2 materials along. 3 Q. And is this experience you -- you had well 4 over a decade ago? 5 A. I'm -- I'm sorry. I don't understand your 6 question. 7 Q. I'll withdraw the question. I think it 8 stands for itself. 9 Exhibit No. 5, the e-mail about the 10 vaginal support device and Prosima device presented on 11 by Marc Slack. 12 Do you see that? 13 A. I do. 14 Q. Is this e-mail about the TVT device? 15 A. No, it's not. 16 Q. Is this e-mail about or relevant to 17 midurethral slings, full-length midurethral slings? 18 A. No. This is about a prolapse procedure. 19 Q. Okay. And it says you were a moderator. 20 Have you moderated presentation sessions 21 here in the United States and abroad on female pelvic 22 medicine and reconstructive surgery? 23 A. Certainly numerous times, yes. 24 Q. And I think you earlier testified that you</p>	<p style="text-align: right;">Page 120</p> <p>1 hundreds of abstracts presented on TVT. In fact, you 2 know, I remember to this day back in 2003 as we were 3 preparing for the joint meeting of the ICS and IUGA 4 2004 in Paris that this scientific committee was being 5 overwhelmed by abstract submissions for TVT and there 6 were over -- for the first time, actually, it was 7 March of 2004, but for the first time all of a sudden 8 we had over 500 abstracts presented on TVT alone. 9 So it became clear to me at that time that 10 the world in 2003, and we were seeing this with the 11 abstracts in 2004, that the world had gained 12 experience with TVT and this is all they wanted to 13 talk about. 14 So our conundrum as a scientific committee 15 at that time was, Well, how are we going to put on a 16 meeting that's not, like, called the TVT meeting, you 17 know, because it was essentially five-sixths of all of 18 abstracts that were being introduced were about TVT. 19 Q. Okay. 20 MS. WATSON: Move to strike as nonresponsive. 21 MR. SNELL: That was responsive to my question 22 in my opinion, so we'll put that out. 23 BY MR. SNELL: 24 Q. You were asked some questions about other</p>
<p style="text-align: right;">Page 119</p> <p>1 were past president of the International 2 Urogynecologic Association? 3 A. Yes, I was. 4 Q. And in that role were you involved in 5 attending and -- or preparing for the annual 6 conferences? 7 A. Oh, yeah, certainly for -- not just when I 8 was president but even more so when I was 9 secretary/treasurer of IUGA for 23 years and then a 10 member of the executive committee for ten years beyond 11 that. 12 Q. And in your roles, responsibilities, 13 participation with regard to these international 14 conferences, did you at any time evaluate or study the 15 TVT device, whether in clinical trials in -- in other 16 people's clinical trials or in any presentations? 17 A. Well, I may not have understood the 18 question. Not specifically in my role as a member of 19 the executive committee at the IUGA meeting, but, yes, 20 year over year going to IUGA meetings, going to ICS 21 meetings, going to American Urogynecologic Society 22 meetings, going to the Society for Urodynamics and 23 Female Urology meetings, and sometimes Society for 24 Gynecologic Surgeons meetings, we heard hundreds and</p>	<p style="text-align: right;">Page 121</p> <p>1 slings that you utilized besides the TVT Retropubic 2 sling? 3 A. Yes. 4 Q. I believe you identified one of the 5 devices, Monarch. 6 Can you just tell us, is that an 7 incontinence sling or some other device? 8 A. Monarch is a transobturator midurethral 9 sling that was produced by American Medical Systems 10 and is no longer in the marketplace. 11 Q. You produced a thumb drive with the 12 materials you've looked at including a lot of the 13 company documents. 14 Based on everything you reviewed, do you 15 still stand behind your opinions that you expressed in 16 your general report? 17 A. Yes. I mean, that was the base -- part of 18 the basis for my general report, so there is nothing 19 that I've learned since completing my general report 20 that's caused me to change my mind in any way. I 21 think at some point I just need to augment my general 22 report. 23 Q. You were asked a little bit about your 24 teaching.</p>

<p style="text-align: right;">Page 122</p> <p>1 Have you taught pelvic surgeons of various 2 levels of experience on midurethral slings such as 3 TVT? 4 A. Yes, I have. I mean, ever since I started 5 doing the operations with TVT first for years and then 6 other devices, I have, of course, as we have alluded 7 to earlier, been teaching our residents and our 8 fellows how to do these procedures. And then, as we 9 touched on in the memo, during the two postgraduate 10 courses I put on every year, I've been teaching 11 individuals how to do these different incontinence 12 procedures, midurethral slings and others, for the 13 last 32 years. 14 MR. SNELL: I believe that is all I have. 15 Thanks. 16 FURTHER EXAMINATION 17 BY MS. WATSON: 18 Q. Doctor, I have just a few follow-up 19 questions. 20 Is it your testimony that since you 21 stopped using the TVT Retropubic in 2005 to 2007 that 22 the TVT Retropubic has not been available at Rush 23 NorthShore Medical Center? 24 A. Well, I didn't hear the very beginning of</p>	<p style="text-align: right;">Page 124</p> <p>1 it's been about three to four years that literally it 2 wasn't available if I wanted to use it, but I'm not 3 positive of the timeline. 4 Q. Okay. So from 2005, '6 or '7 when you 5 stopped using the TVT Retropubic to three to four 6 years ago, why did you not use the TVT Retropubic? 7 A. Because at that point I had used Advantage 8 Fit as my retropubic midurethral sling for the 9 majority of my -- vast, vast majority of my cases and 10 I was really happy with it, so I didn't really feel 11 the need to switch back. And -- 12 Q. Okay. So is it your -- during that time 13 period did you prefer the Advantage Fit over the TVT 14 Retropubic? 15 MR. SNELL: Object. 16 BY THE WITNESS: 17 A. I really wasn't making a comparative 18 decision. 19 Part -- you know, there is another part. 20 As a teaching attending in a fellowship program, I 21 also try to do different procedures at times to expose 22 our fellows and residents to different instrumentation 23 and different techniques. And so for a large part of 24 that period of time when I stopped and -- and -- and</p>
<p style="text-align: right;">Page 123</p> <p>1 the question and there is -- and I practiced at Rush 2 Medical College and Rush Presbyterian St. Lukes 3 Hospital from 1986 through 19 -- March 1991, but I 4 don't work there any longer. 5 I think what you are getting at is, were 6 you trying to ask me when did I no longer have the 7 availability of TVT to use? 8 Q. Yes and no, but your CV indicates that you 9 currently have privileges for hospital staff 10 appointments at Rush NorthShore Medical Center from 11 1991 to present. 12 Is that not true? 13 A. Sorry. Yeah. So Rush NorthShore Medical 14 Center was bought by my employer NorthShore University 15 HealthSystem and it is now called Skokie Hospital and 16 so I do have privileges there, but it is a different 17 organization. And I'm sorry. That's just one of the 18 ways my CV is incomplete. So, sorry to confuse you. 19 Q. Okay. That's fine. 20 A. Yeah. 21 Q. I guess to just cut to the chase, when was 22 the TVT Retropubic no longer available to you in your 23 practice? 24 A. Yeah, I can't be too exact, but I think</p>	<p style="text-align: right;">Page 125</p> <p>1 TVT was still available to us, one of my partners was 2 almost exclusively only using TVT. So our fellows and 3 our residents were learning how to do TVT from her and 4 so I didn't feel like I needed to do that. And so I 5 was focusing on using some other devices that she and 6 my other partners didn't use from a teaching 7 standpoint. 8 So -- so the decisions weren't just always 9 what do I want to use independent of any other factor. 10 Sometimes it was, are we teaching our fellows to do 11 enough Burch procedures, are we teaching them enough, 12 you know, bladder neck slings, the different things 13 that they are responsible to learn to meet their 14 educational guidelines for their fellowship. 15 BY MR. WATSON: 16 Q. But in treating patients, isn't your 17 primary responsibility and goal to use the safest and 18 most effective product for that particular patient in 19 treating stress urinary incontinence? 20 A. Of course it is. Of course it is. But I, 21 personally, when I was looking at TVT and Advantage 22 Fit, I was looking at them as equivalent products. 23 And in my personal experience as well as the limited 24 literature on Advantage Fit, there was no reason to</p>

<p style="text-align: right;">Page 126</p> <p>1 presume or assume otherwise.</p> <p>2 So I looked at them from a patient safety</p> <p>3 and efficacy standpoint as equivalent devices, but</p> <p>4 when you asked me why wasn't I sometimes using TVT, it</p> <p>5 was because I didn't really need to on the educational</p> <p>6 front because one of my partners was using that</p> <p>7 exclusively.</p> <p>8 Q. Okay. But just to be clear, you've</p> <p>9 testified that -- that you stopped using it in</p> <p>10 somewhere between 2005 and 2007, but it was available</p> <p>11 to you until three to four years ago, is that correct?</p> <p>12 A. That is correct, yes.</p> <p>13 MS. WATSON: I have no further questions. Thank</p> <p>14 you for your time, Doctor.</p> <p>15 THE WITNESS: Surely.</p> <p>16 MR. SNELL: Well, I have one, then, since you</p> <p>17 kind of raised this and gone back into it.</p> <p>18 FURTHER EXAMINATION</p> <p>19 BY MR. SNELL:</p> <p>20 Q. Have you seen any reliable medical</p> <p>21 literature that -- any other full-length retropubic</p> <p>22 sling you've used, like the Boston Scientific</p> <p>23 Advantage, is actually more effective than TVT?</p> <p>24 A. No. There is no medical literature that</p>	<p style="text-align: right;">Page 128</p> <p>1 REPORTER'S CERTIFICATE</p> <p>2</p> <p>3 I, JULIANA F. ZAJICEK, C.S.R. No. 84-2604,</p> <p>4 a Certified Shorthand Reporter, do hereby certify:</p> <p>5 That previous to the commencement of the</p> <p>6 examination of the witness herein, the witness was</p> <p>7 duly sworn to testify the whole truth concerning the</p> <p>8 matters herein;</p> <p>9 That the foregoing deposition transcript</p> <p>10 was reported stenographically by me, was thereafter</p> <p>11 reduced to typewriting under my personal direction and</p> <p>12 constitutes a true record of the testimony given and</p> <p>13 the proceedings had;</p> <p>14 That the said deposition was taken before</p> <p>15 me at the time and place specified;</p> <p>16 That I am not a relative or employee or</p> <p>17 attorney or counsel, nor a relative or employee of</p> <p>18 such attorney or counsel for any of the parties</p> <p>19 hereto, nor interested directly or indirectly in the</p> <p>20 outcome of this action.</p> <p>21 IN WITNESS WHEREOF, I do hereunto set my</p> <p>22 hand on this 3rd day of October, 2018.</p> <p>23</p> <p>24 JULIANA F. ZAJICEK, Certified Reporter</p>
<p style="text-align: right;">Page 127</p> <p>1 I'm aware of that suggests that Advantage Fit is more</p> <p>2 effective or safer than TVT. And actually, recently,</p> <p>3 I was introduced to a paper I hadn't known about, a</p> <p>4 case series, which suggested that Advantage Fit might</p> <p>5 have a higher erosion rate. It wasn't -- that's not</p> <p>6 consistent with my experience, but it showed a higher</p> <p>7 erosion rate than the TVT procedure.</p> <p>8 Q. So if Plaintiff was to suggest or try to</p> <p>9 portray your usage of TVT and other retropubic slings</p> <p>10 over time as you having a concern with TVT that it was</p> <p>11 not safe or effective, would that be not accurate?</p> <p>12 A. Correct, that would not be accurate.</p> <p>13 There is no medical literature to suggest that, and</p> <p>14 when we've looked back retrospectively at our own data</p> <p>15 for various reasons and various research papers and</p> <p>16 abstracts, we have not shown any difference in TVT and</p> <p>17 Advantage Fit, and when we've published, specifically</p> <p>18 we've actually shown that TVT was more effective than</p> <p>19 some other procedures that we had used in the past.</p> <p>20 MR. SNELL: Thank you. No further questions.</p> <p>21 MS. WATSON: I have no further questions. Thank</p> <p>22 you, Doctor.</p> <p>23 (Time Noted: 12:19 p.m.)</p> <p>24 FURTHER DEPONENT SAITH NOT.</p>	